ENVIRONMENTAL ASSESSMENT

FOR THE

BL-3 LABORATORY

AT

BATTELLE'S MEDICAL RESEARCH AND EVALUATION FACILITY

June, 1993

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EXECUTIVE SUMMARY

DESCRIPTION OF THE PROPOSED ACTION

The proposed action described in this environmental assessment (EA) is the renovation of an existing building into a laboratory to evaluate the efficacy of candidate medical countermeasures in preventing the effects of toxins that could be used by a hostile force conducting biological warfare (BW) against U.S. troops. Research, development, test, and evaluation (RDT&E) conducted at this laboratory will comply with U.S. Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Guidelines and meet Biosafety Level Three (BL-3) biocontainment criteria published by the Centers for Disease Control (CDC) and the National Institutes of Health (NIH). The U.S. Army (DA), which is the executive agent for the Department of Defense (DoD), Biological Defense Research Program (BDRP), plans to fund the building renovation and research under two existing contracts with Battelle Memorial Institute. The proposed BL-3 Laboratory will be established within the middle area of Battelle's 1,184-acre research complex at a rural location near West Jefferson, Ohio.

ALTERNATIVES TO THE PROPOSED ACTION

Five alternatives to the proposed action were considered: (1) use an existing DA facility instead of Battelle (no action alternative), (2) use parenteral exposure to avoid aerosol generation, (3) use a refined screening procedure to reduce quantities of aerosolized toxin used, (4) use *in vitro* rather than *in vivo* tests, and (5) use a contractor other than Battelle. From a national defense standpoint, the major advantage of the proposed action compared to all five alternatives is the expedient development and FDA approval of effective medical countermeasures to protect against toxin threats to U.S. troops.

The advantage of Alternatives (1) and (5), to use an existing DA facility or a contractor other than Battelle, would be to eliminate any possibility of an accident at the Battelle facility.

Disadvantages of these two alternatives are that the accident possibility for the required work would shift to the DA facility or another contractor, the option of using Battelle's extensive

GLP expertise and aerosol generation technology would be lost, and the development and approval of medical countermeasures for toxins could be delayed.

The advantages of Alternatives (2) and (4), to use parenteral exposure or *in vitro* testing, would be to decrease the quantities of toxin used and eliminate the use of aerosols, which would lessen the maximum credible event (MCE) and would only require Biosafety Level Two (BL-2) biocontainment. Disadvantages of the these alternatives are that they do not adequately mimic the expected field exposure route and they would delay development and approval of medical countermeasures for toxins.

The alternative to use a refined screening process (i.e., combined *in vivo* testing and computer simulation) could decrease the amount of toxin used in testing, which would reduce the MCE. The disadvantage of this alternative is that no validated technology exists currently to evaluate the treatment efficacy parameters that would be required in these tests. A major effort in the proposed laboratory would consist of performing detailed tests to establish and validate new protocols and to reduce animal requirements based
on Battelle's stage-wise adaptive experimental design technology which would meet technical standards, reduce cost per test, and improve the rate of countermeasure development.

ENVIRONMENTAL CONSEQUENCES AND MITIGATION MEASURES

This EA finds that no significant adverse impact on human health or the environment is anticipated from BL-3 laboratory establishment, normal operations, or in the unlikely event of a MCE accident. If an MCE should occur with botulinum toxin, only minute quantities (O.9 pg) of this toxin would be released from the ventilation discharge point. Even before dilution in the biological safety cabinet and in the atmosphere, the MCE release quantity is below the estimated maximum permissible dose (MPD) of 10 pg. which is a dose considered to be safe for human

exposure. Impacts from normal operations include release of insignificant levels of regulated air and water emissions (not toxins) at levels below permitted limits and the consumption of

electricity and natural gas. Depending upon the level of effort, up to eight staff members, mostly Madison County or Franklin County residents, would be needed to operate the laboratory. This will have no appreciable effect on the local economy. No effects on cultural or historic resources and no land use conflicts are expected, since an existing building will be renovated.

Mitigation measures to reduce the risk of accidents and reduce the risk of release of a toxin in the event of an accident at the proposed BL-3 laboratory include safety management programs, staff training, designated safety personnel, secured areas, standing operating procedures (SOPs) for handling toxins, laboratory design including special hoods, exhaust filtration systems, and sealed drains to contain any spills within the laboratory. The DA will also conduct semi-annual inspections and other periodic, random, inspections, reviews, staff assistance visits, etc., to insure that the safety procedures are being followed as specified in SOPs and that the equipment meets appropriate safety standards.

If an MCE accident occurred causing release of toxin, the total amount released before dilution in ambient air is below the level considered safe for human inhalation. In addition, the public would be informed of the extent and magnitude of the event. This is perhaps the best way to discourage the dissemination of incorrect information and eliminate the formation of unfounded socioeconomic concerns about potential human health impacts. Thus, no additional mitigation is necessary.

No significant, non-mitigatable environmental effects associated with the proposed action were identified for normal operation or a MCE accident. Since toxins are purified extracts from living organisms and cannot replicate, there is no risk of infection, release of organisms, or of increasing the amount of toxin due to multiplication of organisms.

1.0 PURPOSE AND NEED FOR THE PROPOSED ACTION

1.1 INTRODUCTION

The U.S. Army Medical Research and Development Command (USAMRDC) representing the U.S. Army, the executive agent for the Biological Defense Research Program BDRP) of the Department of Defense (DoD), plans to renovate an existing building into a laboratory to evaluate the efficacy of candidate medical countermeasures in preventing the effects of toxins that could be used in biological warfare (BW). Test and evaluation conducted at this facility must comply with U.S. Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Guidelines (FDA, 1989) and the laboratory must meet Biosafety Level Three (BL-3) biocontainment criteria. USAMRDC plans to establish the BL-3 test and evaluation laboratory on land owned by their contractor, Battelle Memorial Institute, at a rural site near West Jefferson, Ohio (Figure 1-1). The proposed laboratory will be established and operated under two existing USAMRDC contracts with Battelle: building renovation - DAMD17-89-E-9001 and operation - DAMD17-89-C-9050.

Army Regulation (AR) 200-2 [U.S. Department of the Army (DA), 1988], which implements regulations by the Council on Environmental Quality (CEQ) under the National Environmental Policy Act (NEPA), requires that the DA identify and consider the environmental impact of DA actions in such a way as to minimize or avoid potential adverse effects on human health or the environment. In compliance with these requirements, the USAMRDC has directed preparation of this EA for the BL-3 laboratory to be established near West Jefferson, Ohio. This evaluation will be used to determine if the proposed action (establishment and operation of a BL-3 laboratory to evaluate the efficacy of medical countermeasures against toxins) requires an EIS.

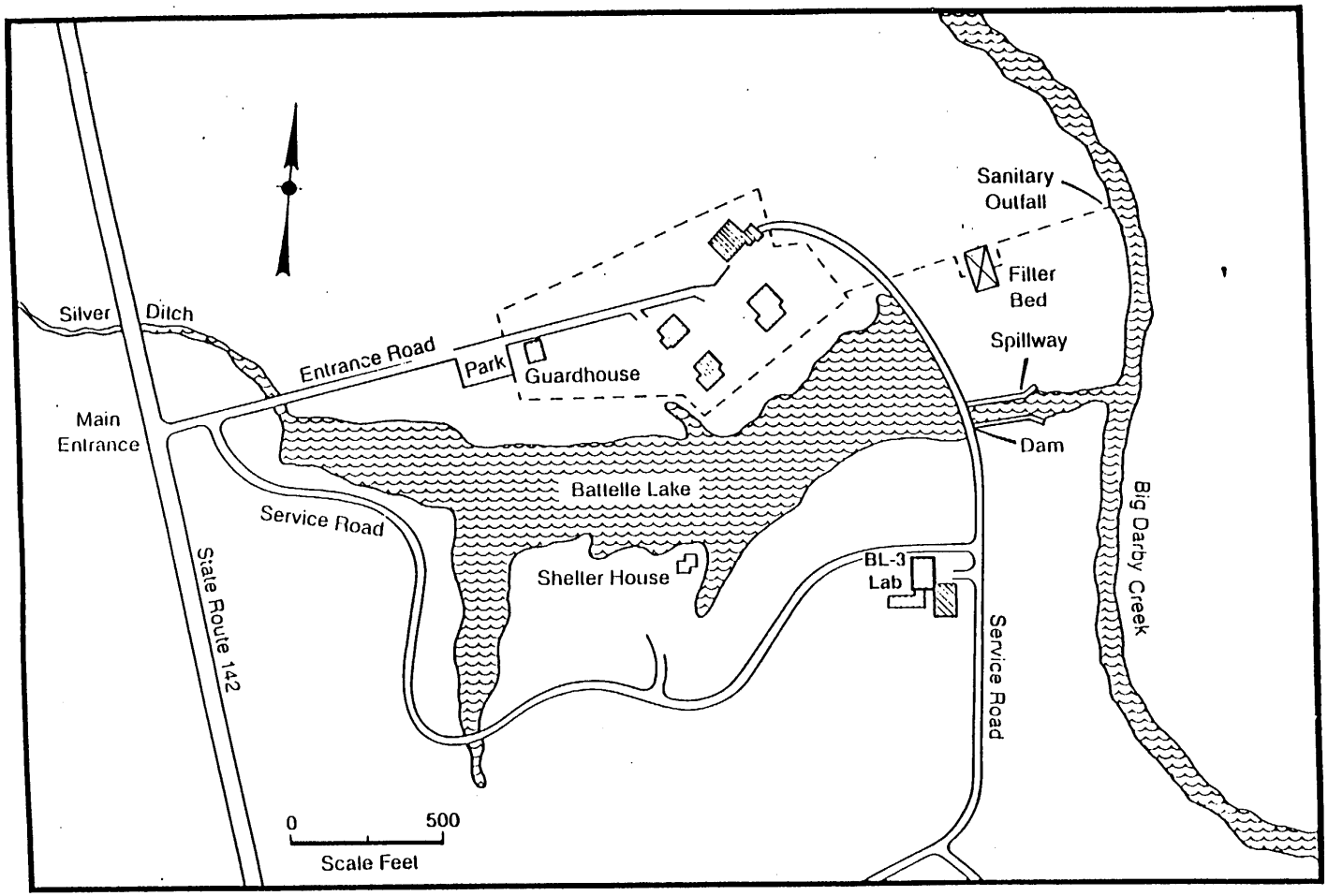

FIGURE 1.1 LOCATION OF THE PROPOSED BL-3 LABORATORY AT BATTELLE'S WEST JEFFERSON RESEARCH COMPLEX

1.2 PURPOSE AND NEED

The USAMRDC is tasked with investigating the medical aspects of the BDRP; this portion of the overall program is referred to as the Medical Biological Defense Research Program (MBDRP). The MBDRP is a Research, Development, Test, and Evaluation (RDT&E) program conducted by DoD, with the DA serving as the executive agent for the whole BDRP. The proposed BL-3 laboratory will be part of the ongoing MBDRP.

The objectives of the MBDRP are to develop measures for identification and decontamination of BW threat agents, and to develop means to protect from, diagnose, or treat intoxications from these agents. Development of medical defensive measures, such as prophylactic vaccines, toxoids, drugs, therapeutic measures, and patient treatment/management protocols are important components of the MBDRP. The purpose of the MBDRP is to maintain and promote a solid national defense posture with respect to BW threats. The MBDRP supports RDT&E efforts necessary for the development and maintenance of defensive measures and materiel to meet these threats. In addition to promoting the national defense posture, the MBDRP benefits the scientific community in general through its research and development efforts, and benefits the global population in the development of diagnostic methods, vaccines, antitoxins, toxoids, and drug therapies.

The DoD prepared a Final Programmatic Environmental Impact Statement (FPEIS) for the continued conduct of the BDRP and filed the FPEIS with the U.S. Environmental Protection Agency (EPA) on April 4, 1989 (USAMRDC, 1989). The FPEIS addressed the overall impact of the BDRP at the programmatic level. The Record of Decision (ROD) of the BDRP FPEIS, dated November 27, 1989, noted questions and differences of opinion regarding the BDRP, as well as concerns about certain aspects of the program such as aerosol testing and genetic engineering. It did not find convincing evidence that the program should be substantially altered or terminated, however, because the impact analysis revealed no significant adverse environmental impact. Minor unavoidable adverse impacts, such as contributions to normal waste streams and potential light health risks to the workforce, were outweighed by the importance of the

program to national defense. The standard operational, safety, security, and regulatory controls, which are based upon federal, state, and local laws and institutional criteria, serve to mitigate any potential adverse impact resulting from normal activities. Any risks inherent in the conduct of the BDRP, are ameliorated through the implementation of these control measures.

This EA is tiered to the FPEIS for the BDRP, (USAMRDC, 1989). Issues which were addressed at the programmatic level in the FPEIS will be included in this EA only by reference to the FPEIS. The specific impacts potentially resulting from establishment of the proposed BL-3 laboratory at Battelle's West Jefferson research site were not addressed in the FPEIS. Therefore, this EA will consider the potential impact resulting from both the specific location and the RDT&E planned for the proposed BL-3 laboratory.

The proposed BL-3 laboratory will be established by renovation of an existing laboratory facility located on Battelle's 1,184-acre research complex near West Jefferson, Ohio, in a rural area approximately 17 miles west of Battelle's King Avenue facility in Columbus, Ohio. The proposed BL-3 laboratory will be located in the middle research area in the east-central portion of Battelle's research complex (Figure 1-1).

The RDT&E to be conducted at the proposed BL-3 laboratory will support the MBDRP efforts for protecting against the effects of toxins that could be used against U.S. troops in BW by a hostile force. The purpose of this RDT&E is to provide the documentation needed to obtain FDA approval for medical countermeasures to be used to protect against toxin threats. The protocols used at the proposed BL-3 laboratory will meet the GLP research requirements that are necessary to obtain FDA approval and will be used to validate results of other studies conducted by the DA. It should be noted that only toxins extracted from microorganisms, other animal species, or plants will be used in the experiments. The extracted toxins will be obtained from the DA or from commercial sources. Since no live organisms will be used, the proposed action poses no risk of infection, release of organisms, or of increasing the amount of toxin due to multiplication of organisms.

1.3 LITERATURE CITED

Food and Drug Administration, Department of Health and Human Services, 1987. Good Laboratory Practice Regulations: Final Rule. Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies. Federal Register, 21 CFR Part 58.

U.S. Department of the Army, 1988. Environmental Effects of Army Actions. Army Regulation (AR) 200-2, Update, Headquarters, Department of the Army, Washington, D. C. 23 December. UNCLASSIFIED Report.

U.S. Army Medical Research and Development Command (USAMRDC), 1989. Final Programmatic Environmental Impact Statement: Biological Defense Research Program. U.S. Army Medical Research and Development Command, Department of the Army, Fort Detrick, Frederick, MD. April. UNCLASSIFIED Report.

2.0 DESCRIPTION OF THE PROPOSED ACTION

The proposed action is the establishment and operation of a BL-3 laboratory at Battelle's West Jefferson research complex. RDT&E at the laboratory will involve toxin aerosol challenges of laboratory animals in order to evaluate the efficacy of candidate medical countermeasures, such as toxoids.

2.1 DESCRIPTION OF FACILITIES

The proposed BL-3 laboratory will be located within a 1,184-acre tract of land owned by Battelle Memorial Institute in a rural area approximately 17 miles west of Battelle's Columbus, Ohio campus and about 8 miles west of the I-270 outerbelt around metropolitan Columbus. The tract is divided into three functional areas: a north site, a middle site, and a south site. The work conducted for the MBDRP will be conducted in a BL-3 laboratory, which will be located within the middle site in Building JM-1.

A map of Battelle's West Jefferson Research Complex was provided in Chapter 1 (Figure 1-1), and a floor plan of the proposed BL-3 laboratory is shown in Figure 2-1. The proposed BL-3 laboratory is constructed of masonry with a steel bar Joist and built-up roof. The BL-3 research area within the proposed laboratory is designed to meet or exceed the BL-3 laboratory guidelines published by the CDC and the NIH (Richardson and Barkley, 1988) entitled "Biosafety in Microbiological and Biomedical Laboratories". Additionally, all of the animal research, holding, and support facilities will meet or exceed the guidelines established by the U.S. Department of Health and Human Services (1985) and the American Association for Accreditation of Laboratory Animal Care (AAALAC). The portion of the building dedicated to this use will consist of approximately 17,880 ft^2 divided into five major areas: BL-3 exposure area, BL-3 post exposure area, BL-3 support area, administrative area, and mechanical area.

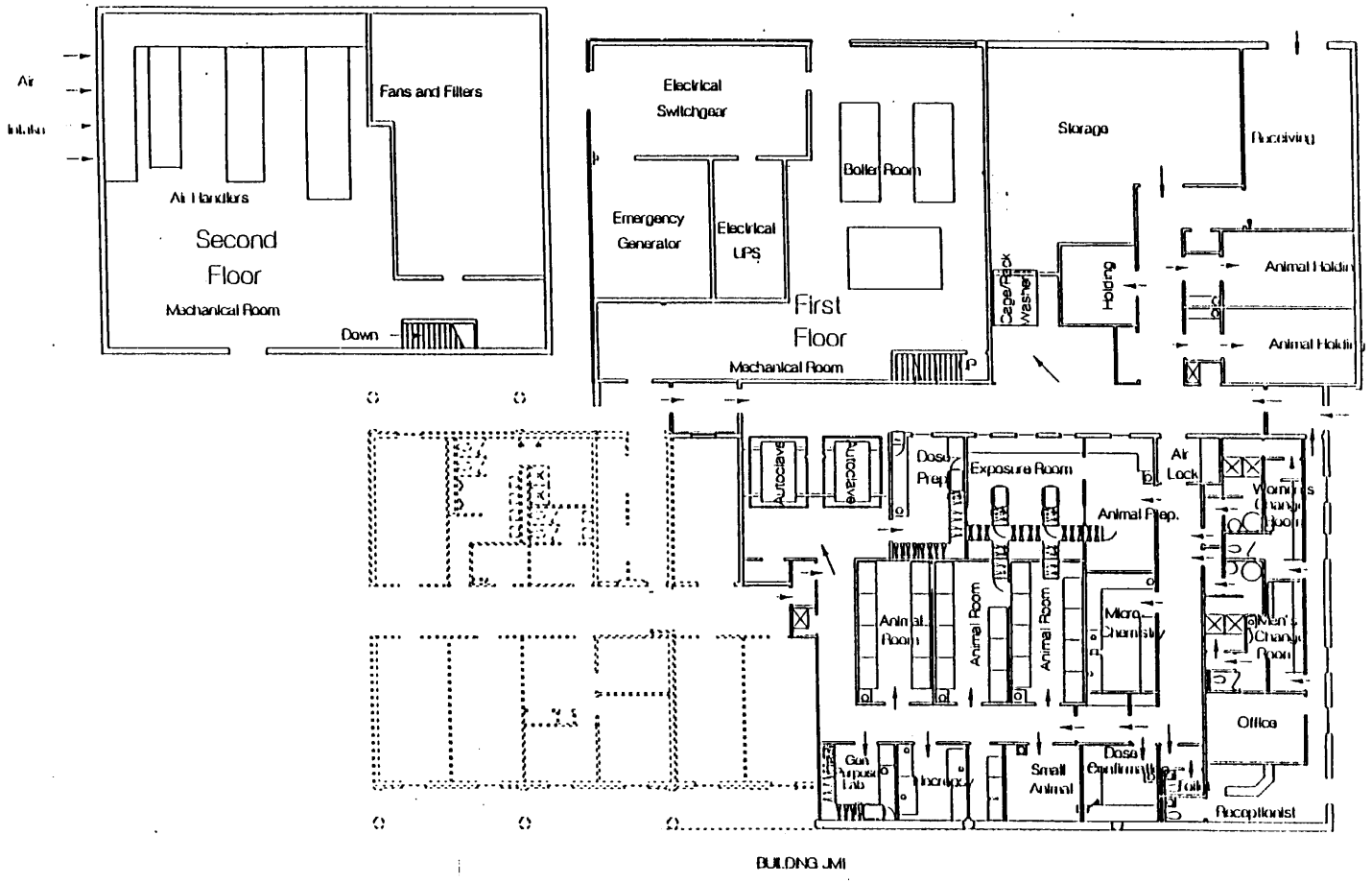

FIGURE 2-1. FLOOR PLAN AND AIR FLOW PATTERNS OF THE PROPOSED BL-3 LABORATORY

2.1.1 BL-3 EXPOSURE AREA

The proposed BL-3 exposure area, illustrated in Figure 2-2, will encompass 2,110 ft^2 and consists of an area within the BL-3 laboratory where animals will be exposed to toxins within biological safety cabinets and where supportive manipulations will only include small quantities of toxins inside biological safety cabinets. The design accommodates a one-way flow of air through the air locks into the BL-3 exposure area hallway and then into the laboratories or animal rooms, where the air exits to high efficiency particulate air (HEPA) filters in the mechanical area (see Section 2.3.7.5). Additionally, the air exiting the animal rooms and biological safety cabinets will be HEPA filtered at the source before being HEPA filtered in the mechanical area. Staff will exit the area through an air lock into the shower area and through a second air lock into the change/toilet area.

Included in the proposed BL-3 exposure area is an exposure laboratory, which will be equipped with Class III biological safety cabinets and two small autoclaves. The Class III cabinetry in the exposure laboratory will connect with Class III cabinetry in the animal rooms, animal preparation room, and the dose preparation room. Additional laboratories within this area will include an animal preparation room equipped with a Class III biological safety cabinet pass-box, a microchemistry laboratory equipped with a Class II and connected Class III biological safety cabinets, and a dose confirmation room equipped with a Class I biological safety cabinet designed with a pass-through to the small animal holding room. This area will also include air locks for entry and exit, an airlock to the BL-3 post exposure area, two shower/change/toilet areas, and a toilet.

2.1.2. BL-3 POST EXPOSURE AREA

The proposed BL-3 post exposure area, illustrated in Figure 2-3, is a specialized area that will encompass 2,740 ft^2 and comprise all portions of the laboratory in which exposed animals or the accompanying caging must be handled, even though briefly, outside of the biological safety cabinets, plus the facilities for the receipt and storage of toxins.

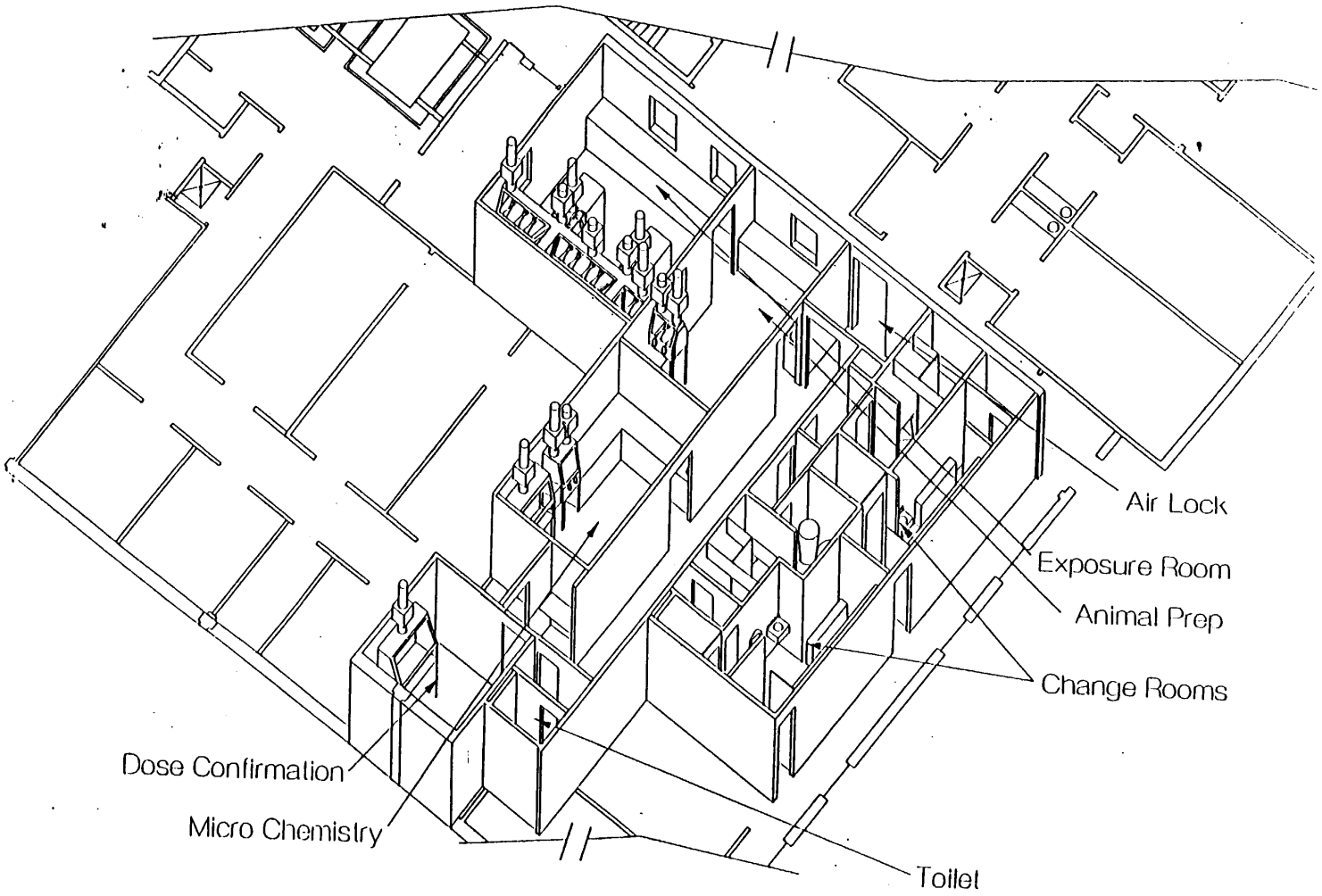

FIGURE 2-2 THE PI-3 EXPOSURE REA[illegible] TU[illegible]

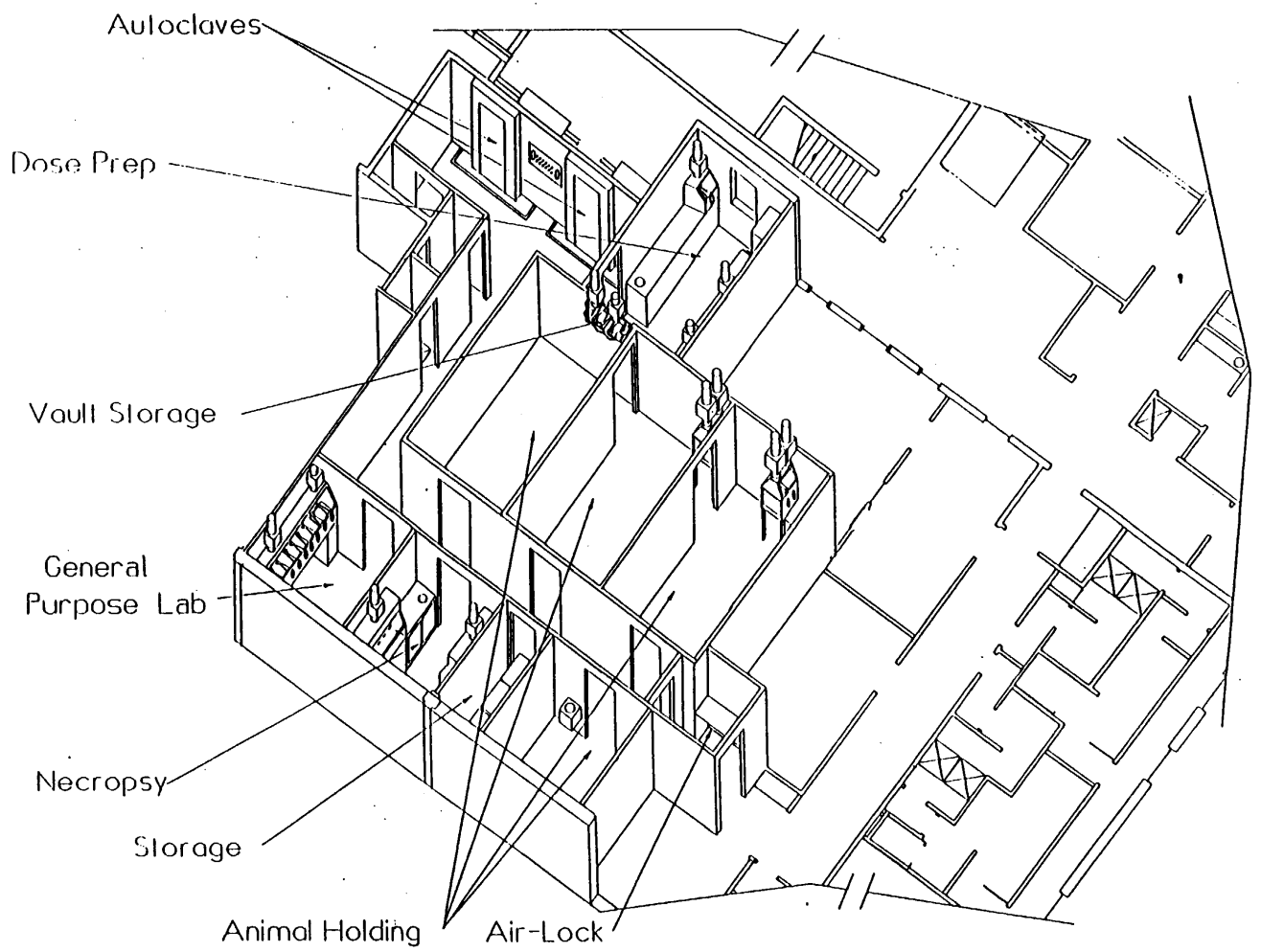

FIGURE 2-3. THE BL-3 POST EXPOSURE AREA OF THE PROPOSED LABORATORY

Personnel working in this area will be required to don additional protective clothing and equipment as they enter, and remove it as they exit into the BL-3 exposure area. The BL-3 post exposure area will be maintained separate from the BL-3 exposure area by an air lock and greater negative pressure than is maintained in the BL-3 area. The BL-3 post exposure area will contain four animal rooms. Three of them are designed to house animals in ventilated animal enclosures while the fourth is designed to house animals in a bioclean enclosure. Two of the animal rooms will be equipped with Class III biological safety cabinets, which will have pass-boxes to remove animals from the exposure cabinetry. The room designed to house animals in bioclean enclosures will have a pass-box to the Class I biological safety cabinet in the dose confirmation laboratory. The BL-3 post exposure area will also include a dose preparation room equipped with a Class III biological safety cabinet, a tornado-proof refrigerator/freezer vault built into the Class III biological safety cabinet for storage of toxins, a small autoclave and a passbox to the hallway in the support area, a necropsy room equipped with two Class I biological safety cabinets, and a general purpose laboratory equipped with a Class III biological safety cabinet. Additionally, the post exposure area will include a cold storage room, a janitor's closet, and an area with two large autoclaves designed to accommodate animal cages and racks.

2.1.3 BL-3 SUPPORT AREA

The proposed BL-3 support area, illustrated in Figure 2-4, will consist of 4,090 ft^2 adjacent to the proposed BL-3 exposure and BL-3 post exposure areas; it is comprised of double-door entries into the main corridor which provides access to the proposed BL-3 areas, three animal holding rooms, a receiving bay, three storage areas, cage wash facilities, a janitor's closet, and an autoclaved waste processing area. Additionally, the main corridor will be provided with windows for viewing the proposed BL-3 laboratory areas and activities.

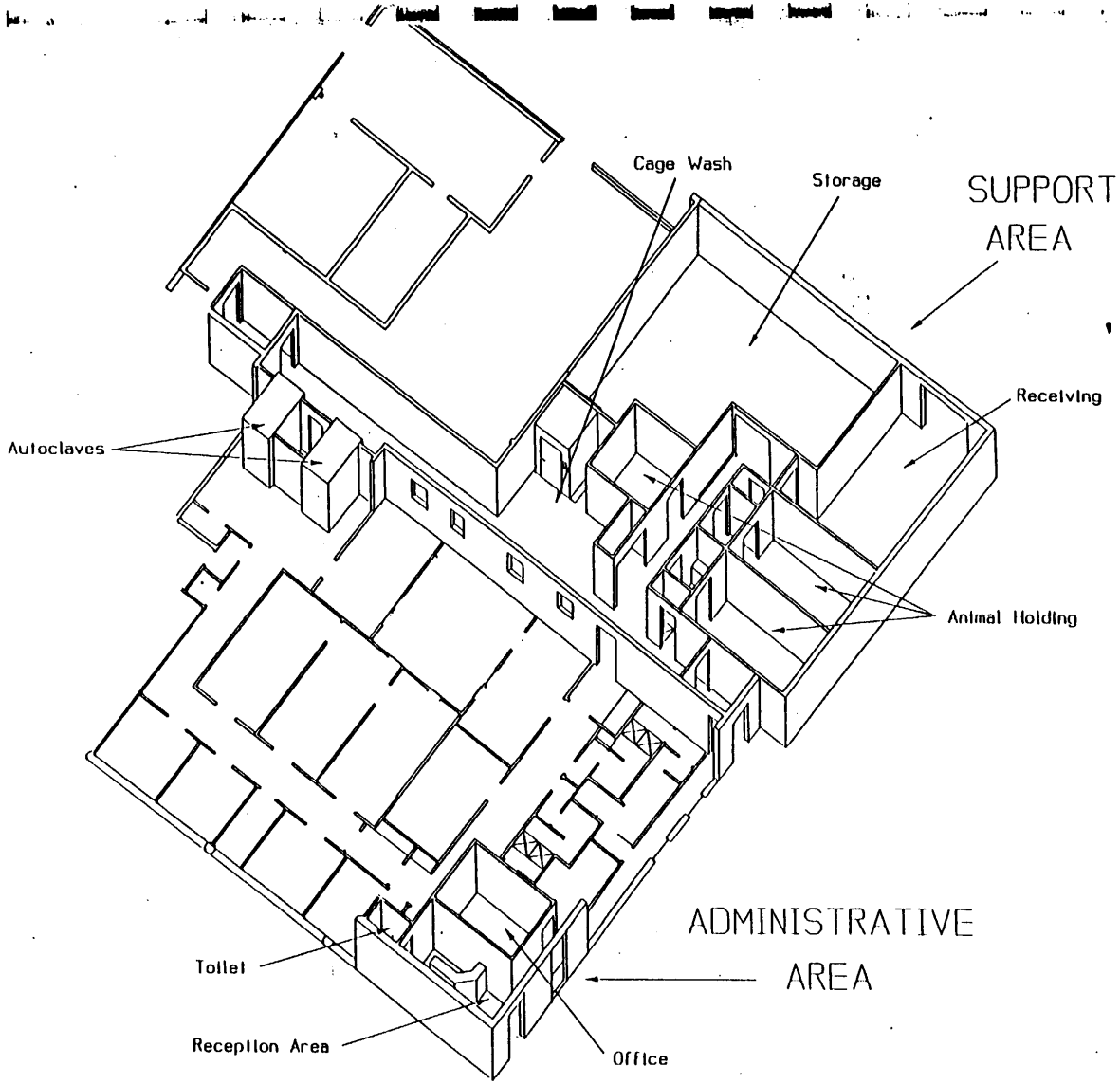

FIGURE 2-4. SUPPORT AND ADMINISTRATIVE AREAS OF THE PROPOSED BL-3 LABORATORY

2.1.4 ADMINISTRATIVE SUPPORT AREA

The proposed administrative support area, illustrated in Figure 2-4, will consist of 700 ft^2 and includes an office, a toilet, and a foyer/receptionist's area.

2.1.5 MECHANICAL SUPPORT AREA

The proposed two-story, mechanical support area, illustrated in Figure 2-5, consists of 8,240 ft^2 and houses: heating, ventilation, and air conditioning systems; electrical systems including a high voltage step-down transformer, an uninterruptible power supply (UPS) with battery back-up, an emergency diesel generator, and supporting transfer systems; and boilers for heat, steam, and hot water; the ventilation exhaust system, with HEPA filters and redundant blowers.

2.2 DESCRIPTION OF THE RESEARCH

The proposed laboratory will support research efforts to determine the efficacy of medical countermeasures, including toxoids, in protecting against toxin threats to U.S. troops. Toxoids create immunity to toxins much like vaccines elicit a protective immune response to microorganisms. However, unlike vaccines which may be derived from attenuated living or killed organisms, toxoids are prepared from chemically treated toxins that no longer have toxicity. Initially, the proposed RDT&E will involve efficacy testing of toxoids that have been developed for botulinum toxin, ricin, and staphylococcal enterotoxin B. These toxoids will be provided to Battelle by the DA.

The main function of Battelle scientists involved in biomedical RDT&E studies within this laboratory will be to develop, validate, and implement *in vivo* methods for assessing the effectiveness of drugs and medical countermeasures against toxins. Whole animal models will be used in this research. Additional studies may include investigations into the safety of medical countermeasures, optimization and duration of protection, metabolic fate, and other animal-based studies to obtain information needed for FDA approval of the countermeasures.

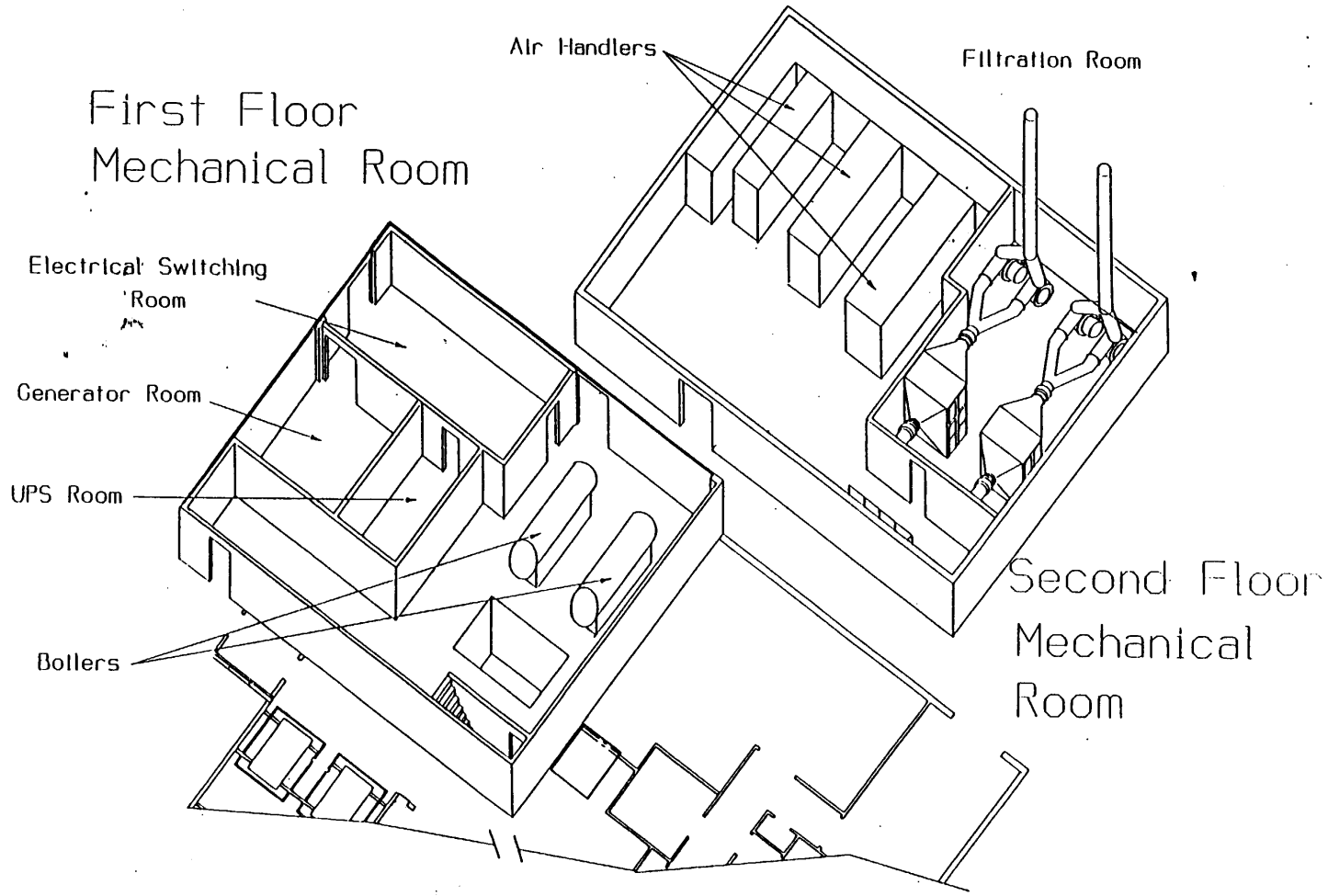

FIGURE 2-5. MECHANICAL AREAS OF THE PROPOSED BL-3 LABORATORY

The countermeasures will be furnished by the DA, while toxins will be provided by the DA or purchased from commercial sources and delivered to Battelle following Department of Transportation regulations. Laboratory animals that are proposed for use in short-term, *in vivo* studies include, but may not be limited to, mice and monkeys. These animals will be provided by licensed commercial laboratory animal producers or by the DA.

2.3 SAFEGUARDS

Extensive safety features have been incorporated into the design and operation of this proposed laboratory. Many of these features, which protect both the worker and the environment, are required by CDC or contract clauses, while others have been added by Battelle to provide additional protection. These safety features consist of engineering controls, protective equipment, operating procedures, and training of personnel. Together they provide a system designed to preclude an accidental release of toxin into a worker's breathing zone or the environment.

This section describes the contribution each of these features makes to the ultimate goal of minimizing the risk of toxin exposure of personnel or a release of toxin from the laboratory. The description includes safety features that involve the toxins from their receipt to the disposal of the waste generated. When relevant, details are provided to confirm the contribution to minimizing the probability or magnitude of a release or exposure. Maintenance and testing schedules that are pertinent to the reliability of these features are also described.

2.3.1 SAFETY PHILOSOPHY

Operation of a laboratory in which hazardous operations occur on a routine basis requires an environment that includes several key elements. First of all, it must be evident to everyone working in the facility that management is completely committed to safety. To do this, management must be knowledgeable of the requirements and demonstrate a genuine concern for the health and safety of personnel. Secondly, the technical staff must be provided with

appropriate training, not only in the hazards, but in the actual means of accomplishing the tasks safely. This must be backed up with skilled management of the personnel to ensure that the required procedures are developed and followed and that the procedures implemented are appropriate and workable. Implementation of these procedures requires guidance, support, and oversight by a competent safety staff. It is also essential that management fully support the safety professionals for them to be effective. Finally, the technical staff needs to feel that they are supported with functional facilities, protective equipment, and clothing that are properly selected and maintained to maximize safety. The personnel that will be assigned to and trained for work at the proposed BL-3 laboratory will be personnel who have a proven safety record and foster strong concern for establishing and maintaining a safe work environment.

2.3.2 SAFETY OVERSIGHT AND GUIDELINES

Safety oversight and safety management of the proposed BL-3 laboratory are provided by an Environment, Safety and Health Officer (ES&HO), who has specific responsibilities for these facilities; as well as by three additional Battelle safety support organizations. The three support organizations are a Safety Committee (SC), a Risk Assessment Committee (RAC), and the Environmental Safety and Health Department (ESHD).

The SC and the RAC establish the general policies and guidelines regarding the scope of the work conducted with hazardous materials. Within the approvals granted, the ES&HO reviews each procedure by conducting a hazard analysis and a dry run of the procedures at the proposed BL-3 laboratory before an SOP is established. Once SOPs that adequately address the concerns of the ES&HO and the operators are written, the procedures must be approved by the ES&HO, management and Quality Assurance before that operation is allowed to commence. If during this SOP review process, potential hazards are noted that are due to procedures beyond current MC and SC approvals, but the process is nonetheless desired by management, both committees must convene to consider whether an amendment to the established policies is warranted. The procedures are

subsequently approved or disapproved based on the decision of the combined committees. Procedures are audited by frequent visits and inspections of the facilities and operations. Should unsafe procedures or acts be observed, the ES&HO has the authority to stop any operation immediately.

2.3.3 STAFF TRAINING

The foundation of a good safety program is safety training and qualified staff. All personnel assigned to the proposed BL-3 laboratory will be selected on the basis of previous experience and/or education. These individuals will then be given extensive training to ensure their readiness to handle their assigned duties. The content of the individual training courses is reviewed and approved by the ES&HO. The staff are given hazard communication, general laboratory, and job specific instruction. The training is supplemented with hands-on training with similar non-hazardous materials, and completed with on-the-job-training (OJT). The OJT begins with duties peripheral to actual toxin handling and may culminate many months later in actual handling of toxins. Records of this training will be maintained by the BL-3 laboratory manager.

2.3.4 FACILITY MANAGEMENT

Facility construction plans and modifications for the BL-3 laboratory are reviewed by the ES&HO to ensure that appropriate safety provisions are provided. To ensure that existing engineering controls supply the safety containment needed, a number of checks and tests are made. Examples of these checks/tests include: biological safety cabinet flow or pressure differential checks, pressure drops between filters, air directionality, di-octyl phthalate (DOP) testing of the HEPA filters, and air pressure differential alarm function tests. Records of these checks and tests will be maintained by the BL-3 laboratory manager.

2.3.5 STANDING OPERATING PROCEDURES (SOPs)

All research at the proposed BL-3 laboratory will require the use of established procedures which have been developed to ensure the safety and well being of the staff. These procedures also apply to the janitorial and laundry activities that are conducted by staff technicians. Currently, approximately 30 SOPs, including the initial project-specific SOP for the handling and use of toxins within the laboratory, are being developed. These SOPs will be fully developed before the laboratory is established; verified by dry-runs of the operations, once the laboratory is available; and evaluated by the staff and the ES&HO. Project-specific SOPs must be approved by the BL-3 laboratory management, the ES&HO, and Quality Assurance before the operation is conducted with toxins.

2.3.6 FACILITIES

2.3.6.1 Access

Access will be limited by the manager of the proposed BL-3 laboratory to individuals whose presence in the laboratory or support area is required to meet program needs. Individuals who are at increased risk or for whom exposure may be unusually hazardous will not be granted access. Access to the laboratory will not be granted until personnel have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization). The standard Battelle badge reader or other similar system will be utilized to control access to the proposed BL-3 support area. Badge readers are activated by staff placing their badge in the reader, which deciphers the code in the badge and electronically compares the code with the list of badges that have been issued to personnel who are authorized access. When matches are found, the door latch is electronically activated, allowing entrance. A code keypad will be placed at the entrance to the proposed BL-3 laboratory area. The combination of the proper badging into the support area combined with the individual access code will allow the air lock to open providing access to the BL-3 areas. The laboratory manager will provide security personnel with a current list of personnel authorized for access to the laboratory. Personnel authorized for access will be trained in the

limitations for visitors and other staff who are not on the access list. Records will be maintained of all personnel that enter the proposed BL-3 area.

To further ensure that the access is limited to authorized personnel, all perimeter doors to the facility will have balance switches on them to indicate when they are opened. These switches will be connected to Battelle's Security Control and Access Center (SCAC) which is staffed around the clock by armed security personnel. Any indication of a breach in the security of the laboratory will activate alarms in the SCAC and armed guards will be dispatched to assess the situation. The emergency exit doors will remain alarmed at all times, while the entrance doors will be deactivated by an authorized individual notifying the security staff when the laboratory is to be accessed. When the laboratory is vacated, personnel will notify the security staff to activate the alarms on the entrance doors.

2.3.6.2 BL-3 Areas

All of the facilities where toxins are handled are located within a secured area to ensure that only authorized personnel gain admittance to the facility. The laboratories are designed to maintain a negative pressure differential relative to the atmosphere and to the hallways. This differential is measured by manometers and alarms sound when the pressure differentials are inadequate. All air that enters the BL-3 area exits through air filtration units. The walls and ceilings are painted with an epoxy paint and the floors are coated with an epoxy finish to serve as a barrier to toxins and facilitate decontamination and routine cleaning. The drains in the BL-3 area are all stoppered to prevent an accidental spill of toxins from being released from the laboratory. Fluids used to wash down or decontaminate BL-3 areas routinely are picked up with a HEPA-filter-equipped vacuum cleaner and processed through the autoclave to ensure decontamination of any traces of toxins that could be present.

2.3.6.3 Biological Safety Cabinets

To ensure the proper containment of toxins, all operations are conducted in Class I, Class II or Class III biological cabinets within the BL-3 area. The cabinets will be specifically designed and built with stainless steel (which is impervious to the toxins) with coved corners to facilitate cleaning, and depressed working areas for containment should a spill occur in the cabinets.

The Class I biological safety cabinets have been selected for use when injecting dilute solutions of toxins (such as to titrate dosages in bioassay procedures), for necropsy, and for rinsing and packaging items. A Class I biological safety cabinet is much like a chemical fume hood with an opening through which air flow is maintained at approximately 100 linear ft/min. To ensure that the Class I cabinets perform to their expectations, the flow rates will be measured by operators before each use, they will be thoroughly evaluated each quarter with certified instruments, and smoke tests to test containment will be conducted annually.

A second type of biological safety cabinet, a Class II, will be used for any *in vitro* assays. The Class II cabinet is similar to the Class I cabinet in that it is an open-fronted cabinet; however, it also has a HEPA filtered airflow inside the cabinet that provides a clean environment for the test items that are placed in the cabinet.

The Class III cabinet was selected for containment of all aerosolized toxins, manipulation of dry powders of toxins, dilutions of stock solutions, and storage, since it provides the best containment available. A tornado-proof vault will be constructed to open inside a Class III cabinet. Upon receipt, and until used, the toxins will be maintained in this vault. A Class III cabinet is a gas-tight glove box, which is a totally enclosed, ventilated cabinet designed for operations to be conducted through attached rubber gloves. Supply air is drawn into the cabinet through HEPA filters and the exhaust air is treated by double HEPA filtration. Rooms in which Class III cabinets are located will be equipped with autoclaves to decontaminate equipment that is removed from them. Class III pass-foxes will also be

attached to the cabinetry in animal rooms to place and remove animals in the cabinet. The pass-boxes are equipped with a sealing doorway that isolates the box from the rest of the Class III cabinet. Once opened to the main Class III cabinet, it is decontaminated before opening to either remove or place an item into the system. To ensure that the Class III cabinets perform as expected, they will be equipped with a manometer that indicates the negative pressure inside the cabinet. Audible and visual alarms will sound whenever the pressure is less than 0.5-inches-water-gauge negative to the surrounding room. These cabinets will be pressure tested annually by the soap bubble/halogen leak test as prescribed in National Sanitation Foundation (NSF) Standard No. 49, Appendix B1 (latest revision June 1987).

A fourth type of biological safety cabinet, a ventilated enclosure cage, will be used in the animal rooms in the proposed BL-3 post exposure area. After an animal is exposed to a toxin aerosol, the exposed area will be rinsed to minimize any toxin contamination that may exist on the animal before removal from the Class III cabinets. Exposed animals will then be placed into the pass-box that opens into one of the animal rooms and covered with a cloth wetted with decontaminant. The animals will be removed from the pass-box in the animal room by personnel wearing protective clothing and placed into specially constructed, ventilated enclosure cages. The cages incorporate a closed system that has a filtered opening through which air enters and a device to which a negative pressure hose can be connected in the animal holding rooms. This will ensure minimal release into the room of any toxins that may be entrained in the fur or exhaled/excreted by the animals.

2.3.6.4 Laboratory Exhaust Filtration System

Aerosolization of toxins into the exposure containment systems within the Class III cabinets could result in the release of toxins into the biological safety cabinets. Thus, it is imperative that the cabinets operate continuously and that any toxin is removed from the exhaust air exiting the cabinets. To accomplish this, a redundant HEPA filtration system is used. The first filter is placed on the exhaust stream exiting the cabinet and the second is located in the mechanical room. Each filter system consists of two complete filtration units that are aligned in series, each containing a pre-filter and a HEPA filter. The HEPA filters ensure that the fine particulates and aerosols of the toxins are removed from the exhausted air.

When new filters are installed in the filtration system, and before operations with toxins are permitted, the filters are tested using DOP to ensure that each filter is performing according to specifications. These tests are performed in accordance with American National Standards Institute (ANSI) N509 (ANSI, 1989) and N510 (ANSI, 1975), which require that HEPA filters allow no more than 0.03 percent of the DOP to pass. This test is performed on individual filters to ensure that a truly redundant system exists. This performance test is repeated every other year. Additionally, the filters are checked periodically by pressure drop across each filter to determine when particulates are beginning to clog the filters thus making replacement necessary. Results of the filter testing will be maintained.

All of the filters outside the BL-3 area are of the modular bag-in, bag-out type. This allows them to be replaced without opening them to the environment. The housings will have valves and fittings that will accommodate the isolation and decontamination of the housings and filters before the filters are removed from the system. The filters will be disposed of by incineration.

2.3.6.5 Exhaust Blowers and Electrical Supply

Air flow patterns that will be established for the laboratory are shown in Figure 2-1. The laboratory, with the exception of the mechanical area, is negative to atmospheric conditions to ensure that directionality of air flow is maintained at all times. The objective is to maintain air flow toward these areas where the highest potential for release of the toxins exist. Thus, for this laboratory, the animal holding rooms will have the greatest degree of negativity, and their negativity will only be surpassed by the Class III cabinets and the animal enclosure cages.

Should the air balance not be maintained in the proposed BL-3 area, containment could be lost, and thus it is prudent to have redundant systems to ensure that air flow is maintained. This is accomplished by redundant blower and electrical supply systems. A primary blower normally exhausts the air, and a second fan is ready to start and take over automatically should the first fan fail to maintain an adequate air flow. If the primary blower were to fail, an alarm would sound in the laboratory, and personnel would be required either to cease operations or to take additional precautions, since there would no longer be an additional backup system.

A sophisticated redundant power supply system will be used to ensure a constant supply of electricity to the exhaust fans and other critical systems in the laboratory. This system consists of commercial power, a diesel powered generator, and a UPS. Normally, power is supplied to the blowers from the batteries in the UPS, with the power level in the batteries maintained by commercial power. If commercial power from the electric company is lost, such as in an electrical storm, the generator automatically starts and picks up the power requirements to maintain the batteries. If a failure in the electrical power line does occur, there will be no interruption in service to the fans since they will continue to be powered by the batteries. Should there be a multiple failure, the fans would be able to maintain the air flow in the hoods using battery power for over 20 min. This allows sufficient time for an orderly shutdown of any operation that may be in progress at the time of the failure. Alarms and procedures will be in place to communicate this failure

and the requirement to shut down operations. Should there be a failure in the UPS, the UPS would automatically be by-passed to the commercial power with the generator as the back-up. If this failure were to occur, an alarm would indicate the UPS failure and appropriate procedures would be taken to minimize risk should a further failure occur.

These power systems are critical to the safety of the operations, and thus require frequent testing and maintenance to ensure that they are available when needed. This maintenance will be performed by a dedicated maintenance staff assigned to the laboratory. Tests will be conducted each month by shutting off commercial power to the UPS and allowing the back-up systems to function as designed. The generator will be run for a full 3 hours, handling the entire system load of the laboratory. Additionally, maintenance personnel will check out all systems and perform any needed maintenance at this time.

2.3.6.6 Safety Alarms

Since the maintenance of airflow patterns and pressure differentials are critical to the containment capabilities of this proposed BL-3 laboratory, an assortment of magnehelics will be properly positioned within the facility so that the appropriate alarms would be activated when the desired pressure differentials are not maintained. Critical pressure differentials that would actuate alarms if not maintained include: (1) pressure between the Class III cabinets and the room, (2) static pressures in exhaust from the Class I and II cabinets, (3) pressures between the laboratory rooms and the hallway, and (4) pressures across air locks. In addition, the mechanical room will be equipped with air pressure differential monitoring equipment and alarms to indicate when air flow through HEPA filtration becomes impeded.

The proposed BL-3 laboratory will have “panic” and fire alarms placed at appropriate locations so that should anyone have an emergency requiring evacuation, or one in which assistance is required, they can activate the appropriate response by pressing an alarm.

2.3.7 PROTECTIVE CLOTHING AND EQUIPMENT

Personal protective equipment (PPE) is selected by the ES&HO and is monitored for adequacy and maintenance. PPE and clothing will be checked by the operators before each use, and by the laboratory facilities manager each month, to identify items needing to be replaced or serviced. The ES&HO will ensure that personnel assigned PPE are properly trained in its use and maintenance.

PPE will be worn either as a back up to the engineering controls or when engineering controls do not completely abate the potential for exposure (e.g., transfer of potentially contaminated animals to containment cages). Additionally, when efficacious toxoids are available and recommended by the Battelle medical staff, these will be used to provide an additional degree of protection.

All personnel, including visitors and supervisory personnel, who enter the proposed BL-3 support area must wear a laboratory coat and safety glasses. In addition, personnel who work in the animal rooms in the BL-3 support area will have to remove their street clothing, don BL-3-specific laboratory clothing and safety shoes before entering the animal rooms. At the end of the day, or upon completion of their duties in this laboratory, they will shower out before donning their street clothes. Additional protective equipment will be required in some cases, depending upon the animal species in the room.

Personnel who enter the proposed BL-3 exposure area in the laboratory must first enter one of the change rooms where they are required to remove their street clothing and don BL-3-specific laboratory work clothes, safety shoes, a laboratory coat, and safety glasses. Personnel working in the BL-3 exposure area who have been immunized will generally not be required to wear additional clothing. Staff who have not been immunized will wear additional clothing and protective equipment to enter this area; furthermore, staff handling animals may be required to wear specific clothing due to the species being handled. Normally personnel (immunized or not) entering the BL-3 post exposure area will augment their clothing with disposable coveralls, hairbonnet, booties,

surgical gloves, and a HEPA filtered respirator before entering the area. Before entering one of the post exposure work areas (research and animal rooms, or the autoclave area), this protection will be further augmented with a second pair of gloves. To exit the BL-3 post exposure work areas to the BL-3 post exposure hallway, personnel will remove their outer gloves and activate a handwashing sink as they exit the work rooms in this area and wash their inner gloves with soap and water. Personnel will then proceed to the airlock door where they will remove their hairbonnet and disposable coveralls depositing them in the waste container before removing their booties as they step into the airlock. In the airlock they will remove the respirator and the gloves before exiting from the airlock into the BL-3 exposure area.

To exit the BL-3 exposure area, personnel will remove any animal-specific protective clothing they are wearing, remove their gloves, and wash their hands as they exit the animal area into the hallway. They will then proceed to the appropriate bathroom entrance and remove their laboratory coat before entering the airlock. Once through the airlock, personnel will remove their respirator, if being worn, placing it in a receptacle. They will then proceed to the area near the showers, remove the rest of their clothing before stepping into the shower, and take a complete soap and water shower. From the shower, they will go through a second airlock to enter the change room where towels and their street clothing are available.

Equipment, naive animals, and supplies will be brought into the laboratory via the receiving bay, and moved to the appropriate storage locations within the support area until ready to be moved into the BL-3 area. The interior door within the receiving bay will be closed before opening the exterior door. Items will be moved into the proposed BL-3 exposure area by placing them in the outer airlock. Personnel placing them in the air lock will then exit the airlock, after which, personnel from within the BL-3 area will open the inner door of the airlock and remove the items. Alternatively, personnel dressed in BL-3 attire may bring the items into the facility with them, but may not exit to obtain additional items without showering and dressing out.

Exposed animals, equipment, disposable clothing, and supplies will either be decontaminated or processed through the autoclave before removal from the proposed BL-3 laboratory. It is anticipated that most items will exit the facility through one of the autoclaves. Reusable items that would be damaged by an autoclave will be chemically decontaminated with solutions that are known to be efficacious. Reusable autoclaved items will be moved directly from the autoclave by personnel in the support area and moved to the cage wash area. Disposable items will be removed from the autoclave by personnel in the support area and placed in appropriate containers for disposal. Disposable items will be moved to the receiving bay where they will be disposed of according to the nature of the waste [e.g., municipal, Resource Conservation and Recovery Act (RCRA), or infectious]. The autoclaves are of appropriate size to accommodate the animal caging systems.

2.3.8 PROPOSED DECONTAMINATION AND WASTE DISPOSAL PROCEDURES

2.3.8.1 Cages and Caging

Cages and cage racks inside the proposed BL-3 post exposure area will be moved to one of the autoclaves and decontaminated. These items will be removed from the autoclave by personnel in the support area and moved to the cage wash area where they will be cleaned for reuse and stored in the storage area.

2.3.8.2 Animal Wastes

The animal cage trays containing wastes will be removed from the cages and placed in the autoclave. The autoclaved waste will be moved to the cage wash area where it will be disposed of in the sanitary sewer lines. The cage trays will be processed as stated above.

2.3.8.3 Animal Room Cleaning

The animal rooms will be periodically washed with a disinfectant. The disinfectant and any rinse will collect on the floor of the animal rooms.

This will be collected with a HEPA-filtered, wet vacuum cleaner and the liquid processed through the autoclave. The autoclaved liquids will be disposed of down the sanitary sewer.

2.3.8.4 Exposed Animals

It is anticipated that exposed animals will be euthanized and placed in heavy plastic bags. The bags will be taken directly from the animal room to the autoclave. The autoclaved animals will be placed in a rigid container designed to transport them to the pathological incinerator in Building JM-3.

2.3.8.5 Equipment

Reusable equipment and items will be processed through the autoclave when possible. When this is not possible, these items will be decontaminated chemically and placed in a plastic bag. If the item is to be removed from the BL-3 post exposure area, the bag will be placed in the airlock to the BL-3 area. Personnel on the BL-3 side of the airlock will rinse the exterior of the bag down with decontaminant before bringing the bag into the BL-3 area. The bag will then be moved to the airlock to the BL-3 support area, where it will be rinsed down with decontaminant and left in the airlock. An individual in the BL-3 support area will place a second bag around the item and remove it from the airlock. It is also anticipated that some items of equipment will remain within the laboratories or Class I or III cabinetry in some degree of contamination for extended periods. These items will be decontaminated to the extent practicable after each use.

2.3.8.6 Disposable Items

Disposable items will be processed through the autoclave before final disposal. (The specific autoclave cycle conditions will be verified to completely decontaminate a specific toxin before routine use.) Once they have been autoclaved, their disposition will depend upon the nature of the item or material. If the material is not a RCRA waste or Ohio “infectious waste” and

it is reasonable to incinerate it (such as animal bedding), these items will be incinerated. Otherwise items will be disposed of as either RCRA, infectious, or municipal waste.

2.3.8.7 Ohio "Infectious Waste"

Although the scope of operations covered by this EA does not include the use of infectious agents in this laboratory, the normal use of laboratory animals creates "infectious waste" as defined in the State of Ohio Solid and Hazardous Wastes regulations. These wastes include "sharps", syringes, animal blood, and solids contaminated with animal blood. The decontaminated blood, or liquids contaminated with blood, will be disposed of down the sanitary sewer. All other items defined as infectious waste will be collected in Infectious Waste bags or sharps containers, and held in the infectious waste storage area in Building JM-3. A contract is maintained with an infectious waste hauler and incineration facility to dispose of this waste each month.

2.3.8.8 Reusable Clothing

The reusable clothing will be collected in a plastic-lined hamper near the shower in the change roams. Personnel will enter the shower and pour a laundry solution (which captains bleach of laundry strength) into the bags. The bags will be tied off and the exterior of the bag sprayed with decontaminant, followed by rinsing in the shower, as it is removed from the facility. The clothing will be cleaned in the laundry facility in Building JM-3 and reissued for use.

2.4 PERMITS AND REGULATIONS

This section addresses the necessary environmental permits and regulations, including Federal (e.g., DoD and DA regulations), Ohio, and local requirements, that are expected to apply to the proposed BL-3 laboratory and its operation. The principal categories covered in this section are air and water, hazardous waste, transportation, and DoD and DA regulations.

Establishment and operation of the proposed BL-3 laboratory will comply with all applicable regulations. Detailed procedures for operating this laboratory will also be developed as discussed below to assure compliance with DoD and DA regulations.

2.4.1 AIR

Under the Clean Air Act, as amended (42 USC 7401 et seq.), permits are required to install and to operate an air emission source. In Ohio, the authority to issue these permits is delegated to the Ohio Environmental Protection Agency (OEPA). The proposed BL-3 laboratory has several potential sources of air pollution.

Two 6.4 MBtu/hr input gas-fired boilers will supply steam for heating, humidification, and general purpose use at the proposed BL-3 laboratory. The planned boilers will normally use natural gas, but will be capable of using a diesel oil back-up fuel supply. These boilers are potential air contaminant sources. A Permit to Install (PTI) these boilers will be applied for with the OEPA prior to installation. Once installed, an application for a Permit to Operate (PTO) will be submitted if it is determined to be necessary by OEPA. Other boilers used for facilities located near the proposed BL-3 laboratory were placed on registration status by OEPA and were not required to be permitted. Therefore, it is likely that OEPA will treat these boilers similarly.

In addition, waste from the proposed BL-3 laboratory which is examined and found to have no hazardous components will be incinerated in the pathological incinerator located in Building JM-3, near the proposed BL-3 laboratory. This incinerator has a capacity to incinerate 200 lb/hr and is used to incinerate the carcasses of laboratory animals and other combustible wastes. A rough estimate of the quantity of non-hazardous waste from the BL-3 laboratory that is expected to be incinerated in the Building JM-3 pathological incinerator is 3200 lb/month during full utilization of the BL-3 facility. The exact quantity of non-hazardous waste will depend on the number and types of tasks conducted during that month.

This incinerator is currently operating. Prior to construction of the incinerator, Battelle applied for and obtained from the OEPA a PTI for an Air Contaminant Source. Following completion of installation, a PTO for an Air Contaminant Source was applied for and obtained, This permit was renewed once and was effective until 11 November 1989. Battelle submitted their application for renewal of the permit in a timely manner; however, OEPA has not acted an the application pending issuance of new regulations for incinerators. OEPA has taken the position that Battelle can continue to operate under the conditions of the expired permit until OEPA responds to the permit application. Ohio Revised Code (ORC) Section 119.06 states that if OEPA fails to respond to an application for renewal of a permit by the time the existing permit expires, the permittee can continue to operate under conditions of the expired permit. Battelle continues to maintain contact with OEPA to determine the status of permit renewal.

2.4.2 WATER

The Federal Water Pollution Control Act, as amended (33 USC 1251 et seq.), requires that liquid effluents must be permitted under the National Pollutant Discharge Elimination System (NPDES). The OEPA is responsible for carrying out the NPDES program and issuing permits.

The proposed BL-3 laboratory will add a new waste source to the existing wastewater treatment plant at West Jefferson. No drains will be used in the toxin handling areas of the proposed BL-3 laboratory. Wastewater will either drain to collection vessels under sinks or be collected by vacuum. Collected wastewater will be chemically or heat (autoclave) sterilized. After sterilization, the water will be discharged to the wastewater treatment plant through the sanitary sewers. Sanitary wastes from the proposed BL-3 laboratory will be released directly to Battelle's wastewater treatment facility for the West Jefferson research site. A rough estimate of the volume of sanitary wastewater from the BL-3 laboratory during full utilization is 100,000 gal/month. The exact volume of wastewater will depend on the number and types of tasks conducted during that month.

Battelle's West Jefferson site holds an NPDES permit (No. 4IN00004*DD) for its outfalls that discharge into Big Darby Creek. This permit was renewed effective June 3, 1991 and expires May 31, 1996. All wastewater from the proposed BL-3 laboratory will be discharged from Outfall 001. The additional waste water source is expected to require an amendment to the existing NPDES permit.

2.4.3 HAZARDOUS WASTE

No permits for handling hazardous waste are likely to be required for the proposed BL-3 laboratory. Battelle's West Jefferson site, however, does have a Hazardous Waste Identification Number issued by the EPA. Laboratory wastes that cannot be incinerated will be packaged and picked up by Battelle's ESHD for disposal at an approved chemical treatment or disposal facility (e.g., presently Chemical Waste Management or ENSCO disposes of hazardous waste, and Browning-Ferris Industries disposes of infectious wastes). Hazardous and infectious wastes are not processed in the pathological incinerator. Ash from the incinerator, therefore, is not hazardous material and is disposed of in a sanitary landfill. A rough estimate of the quantity of hazardous wastes from the BL-3 laboratory is 50 lb/month of RCRA wastes and 48 lb/month of Ohio "infectious wastes" (as defined in Section 2.3.8.7) during full utilization of the facility. The exact quantities of hazardous wastes will depend on the number and types of tasks conducted during that month.

2.4.4 TRANSPORTATION

Toxins will be shipped in DOT-approved containers to the proposed BL-3 laboratory by commercial carriers, other than the Post Office, that provide a signature-secure service. Shipments will comply with all applicable regulations, including Public Health Service Regulations found in 42 CFR part 72 "Interstate Shipment of Etiologic Agents", U.S. Department of Transportation (DOT) Regulations found in 49 CFR parts 172 and 173, and DoD Regulations found in 32 CFR part 627 (DA Pamphlet 385-69). The toxins proposed for use in the laboratory are currently being shipped without incident by commercial carriers for other types of research. There is

currently no indication that any toxin shipment to the proposed laboratory will need to exceed the maximum shipment quantities specified by DOT. However, if the circumstances or regulations should change, alternative shipping arrangements will be made that satisfy both DoD and DOT regulations. Unpacking of primary material containers, handling of material in open containers, and dose preparation will occur in Class III containment cabinets. Material transfers within the laboratory outside biological safety cabinet containment will require that the material be packaged to meet or exceed the DOT requirements.

2.4.5 DoD AND DA REGULATIONS

In addition to compliance with environmental regulations, the proposed BL-3 laboratory will be established and operated in compliance with DoD and DA regulations. The laboratory will follow the requirements in 32 CFR Part 626 (57 FR 11368) “Biological Defense Safety Program” and 32 CFR Part 627 (57 FR 12604) “Biological Safety Program - (Technical Safety Requirements), DA Pamphlet 385-69 (DA PAM 385-69)”. Under contractual clauses, the laboratory is required to comply with NIH Guidelines for Research Involving Recombinant DNA Molecules (51 FR 16958); however, the scope of operations covered by this EA does not involve the use of organisms in the proposed BL-3 laboratory.

A Facility Safety and Security Plan (FSSP) will be developed for the proposed BL-3 laboratory to describe required operating conditions and procedures. Included in this document will be SOPs and Technical Operating Procedures (TOPs) that define both the operational and technical procedures to be followed while conducting research. Laboratory operations, as controlled by the FSSP and associated procedures, will comply with all applicable Federal, Ohio, local, DoD, and DA regulations, including 32 CFR Parts 626 and 627. The FSSP will be reviewed by the USAMRDC Safety Officer to assure that all practices comply with DA and other DoD regulations. Once approved, they will be implemented by Battelle.

Inspections of the proposed BL-3 laboratory operations to assure safety and procedural compliance will be conducted monthly by Battelle's ES&HO. Every six months, officials from USAMRDC will inspect the operating procedures at the proposed BL-3 laboratory to assure compliance with SOPs. Inspections will also be conducted by the Quality Assurance Unit of Battelle. The SOPs are updated periodically (at least annually) and examined by the DA to assure that all current and proposed research complies with all applicable regulations. The safety plan will be kept on file at the proposed BL-3 laboratory. Copies will also be kept by the USAMRDC for reference.

2.5 LITERATURE CITED

2.5.1 REFERENCE DOCUMENTS

American National Standards Institute (ANSI), 1975. Testing of Nuclear Air Cleaning Systems. ANSI N510-1975. The American Society of Mechanical Engineers, New York, NY.

American National Standards Institute (ANSI), 1989. Air-Cleaning Units and Components for Nuclear Power Plants. ANSI N509-1989. American National Standards Institute, New York, NY.

National Sanitation Foundation (NSF), 1987. National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry. Revised June 1987. National Sanitation Foundation, Ann Arbor, MI.

Richardson, J. and W. Barkley (Eds.), 1988. Biosafety in Microbiological and Biomedical Laboratories. Publ. No. (NIH) 88-8395. Centers for Disease Control (CDC) and the National Institutes of Health (NIH), U.S. Department of Health and Human Services, Bethesda, MD.

U.S. Department of Health and Human Services, 1985. Guide for the Care and Use of Laboratory Animals. Publ. 86-23. Prepared for the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, Commission on Life Sciences, National Institutes of Health, U.S. Department of Health and Human Services, Bethesda, MD.

2.5.2 STATUTES AND REGULATIONS

33 USC 1251 et seq., Federal Water Pollution Control Act, as amended by the Clean Water Act of 1977 and the Water Quality Act of 1987.

42 USC 7401 et seq., Clean Air Act, as amended.

42 CFR Part 72, Interstate Shipment of Etiological Agents.

49 CFR Part 172, Hazardous Materials Table. Special Provisions. Hazardous Materials Communications Requirements, and Emergency Response Requirements.

49 CFR Part 173, Shippers - General Requirements for Shipments and Packaging.

51 FR 16958, 1986. Guidelines for Research Involving Recombinant DNA Molecules. 51(88), Wednesday, May 7.

57 FR 11368, 1992. 32 CFR Part 626, Biological Defense Safety Program. 57(64), Thursday, April 2.

57 FR 12604, 1992. 32 CFR Part 627, Biological Safety Program - (Technical Safety Requirements), Department of the Army Pamphlet 385-69 (DA PAM 385-69). 57(70), Friday, April 10.

3.0 ALTERNATIVES CONSIDERED

In order to fulfill the requirements of AR 200-2 for preparation of an EA, reasonable alternatives to the proposed action must be identified and their advantages and disadvantages briefly discussed. For this EA, the proposed action is establishment and operation of a BL-3 laboratory at Battelle's West Jefferson research site. Research planned for the BL-3 laboratory will support the MBDRP by providing data for submission to the FDA on the efficacy of medical countermeasures in protecting against toxin threats, and by validating studies conducted by the DA. In most cases, test exposures will be toxin aerosols in order to mimic the most likely mechanism of release by an aggressor during a threat situation.

The advantages and disadvantages of five reasonable alternatives to the proposed action are briefly outlined below. The five alternatives are: (1) use an existing DA facility instead of Battelle ("no action" alternative), (2) use a parenteral exposure to avoid toxin aerosol generation, (3) use a refined screening procedure to reduce the magnitude of aerosolized toxin, (4) use *in vitro* rather than *in vivo* tests, and (5) use a contractor other than Battelle. For each alternative, the disadvantages outweigh the advantages, resulting in the conclusion that the proposed action is the preferred alternative.

3.1 USE AN EXISTING DA FACILITY INSTEAD OF BATTELLE (NO ACTION ALTERNATIVE)

The "no action" alternative would involve conduct of medical countermeasure RDT&E at an existing DA laboratory rather than at a Battelle facility. The advantage of this alternative would be to eliminate the possibility of an accident involving toxins during operation of a BL-3 laboratory at Battelle. The remote possibility of an accident involving a toxin would simply be shifted from the Battelle laboratory to the DA facility. Four major disadvantages, however, which outweigh the advantage for using an existing DA facility instead of a Battelle laboratory are: (1) RDT&E of badly needed, effective medical countermeasures would be delayed without the additional assistance provided by operation of a BL-3 laboratory at Battelle, (2)

independent validation of DA data would be difficult without RDT&E of medical countermeasures at Battelle, (3) the DA would lose the option of using Battelle's extensive experience with GLP compliance needed to support regulatory submissions to the FDA, and (4) the DA would lose the option of using Battelle's state-of-the-art aerosol generation technology.

3.2 USE PARENTAL EXPOSURE TO AVOID AEROSOL GENERATION

This alternative would involve conduct of medical countermeasure RDT&E using parenteral exposure to eliminate aerosolization of toxins. The advantage of this alternative would be to eliminate aerosolization of toxins during RDT&E of medical countermeasures, which would reduce the potential for accidental release of toxins to the environment. Four major disadvantages, however, which outweigh the advantage to using a parenteral exposure of toxins are: (1) parenteral exposures do not mimic the expected field exposure route; (2) parenteral exposures would create extent, distribution, and duration parameters of toxicity which are different from those of an aerosol exposure; (3) use of a parenteral exposure would make it more difficult to get regulatory approval of the medical countermeasure because the countermeasure would not be tested against the anticipated route of field exposure; and (4) determination of the DA's field medical doctrine requires that data be collected using the anticipated route of exposure.

3.3 USE A REFINED SCREENING PROCEDURE TO REDUCE QUANTITY OF AEROSOLIZED TOXIN

This alternative would involve use of a refined screening procedure (i.e., combined *in vivo* testing and computer simulation) to reduce the quantity of aerosolized toxin required for testing by changing the test protocol. The advantage to this alternative is that it could reduce the quantity of aerosol available for accidental release to the environment. However, two disadvantages which outweigh the advantage to this alternative are: (1) no validated technology is presently available to evaluate medical countermeasures using any other protocol, and (2) there would be difficulty in correlating test results using simulated or refined treatment efficacy parameters with those required currently to evaluate efficacy for field

exposure scenarios. A major effort in the proposed laboratory would consist of performing detailed tests to establish and validate new protocols to reduce animal requirements based on Battelle's stage-wise adaptive experimental design technology which would meet technical standards, reduce cost per test, and improve the rate of countermeasure development.

3.4 USE *IN VITRO* RATHER THAN *IN VIVO* TESTS

This alternative would use *in vitro* rather than *in vivo* test methods. The advantage to this alternative is that much smaller amounts of toxin would be needed per test, which would reduce the potential for accidental release of toxins to the environment. However, four major disadvantages which outweigh the advantage to this alternative are: (1) the effects of medical countermeasures and toxins on the body are integrated and cannot be simulated by *in vitro* models at present; (2) it is not possible to correlate results of *in vitro* test methods with field levels of exposure; (3) determination of the DA's field medical doctrine requires that data be collected using the anticipated route of field exposure; and (4) historically, *in vitro* efficacy test results have not been accepted by the FDA for approval of new drugs and medical countermeasures, such as toxoids.

3.5 USE A CONTRACTOR OTHER THAN BATTELLE

This alternative involves conduct of medical countermeasure RDT&E at a BL-3 laboratory run by another contractor rather than at Battelle. The advantage of this alternative would be to eliminate the possibility of an accident involving toxins during operation of a BL-3 laboratory at Battelle. The remote possibility of an accident involving a toxin would simply be shifted from the Battelle laboratory to the alternate contractor's laboratory. Four major disadvantages, however, which outweigh the advantage for using an alternate contractor's laboratory instead of a Battelle laboratory are: (1) development of badly needed, effective medical countermeasures would very likely be delayed without the additional assistance provided by operation of a BL-3 laboratory at Battelle, since there are very few other qualified contractors and they are expected to already be operating near capacity;

(2) the DA would lose the option of using Battelle's extensive experience with GLP compliance needed to support regulatory submissions to the FDA; (3) the DA would lose the option of using Battelle's state-of-the-art aerosol generation and stage-wise adaptive experimental design technologies; and (4) in the extremely unlikely event of an accident involving release of toxin, Battelle's West Jefferson site is remote from any major population center, whereas many of the other qualified contractors are located in major metropolitan areas.

4.0 AFFECTED ENVIRONMENT

This section describes both the natural and man-made environment in the vicinity of the proposed BL-3 laboratory that has a potential to be affected by renovation and operation of the laboratory.

4.1 NATURAL ENVIRONMENT

The natural environment of the proposed BL-3 laboratory encompasses the geohydrologic conditions of the area, the atmospheric conditions, and the biota.

4.1.1 TOPOGRAPHY, GEOLOGY, AND SOILS

The topography in the area of Battelle's West Jefferson research site varies from flat to undulating. The site itself is transected by the stream channels of Silver Ditch and Big Darby Creek which are to the north and east of the proposed BL-3 laboratory, respectively. Silver Ditch has been impounded to form Battelle Lake (see Figure 1-1). Elevation ranges from about 900 ft above mean sea level (MSL) at the proposed BL-3 laboratory to about 860 ft above MSL in the Big Darby Creek floodplain.

Battelle's West Jefferson research site is on glacial till approximately 40 to 160 ft thick. The till overlies limestone, dolomite, and shale bedrock several hundreds of ft thick. There have been no recorded earthquakes within 50 miles of the site although a strong quake was experienced in 1937 at Anna, Ohio, a little over 50 miles to the northwest of the West Jefferson site. The West Jefferson site is considered to be in a Zone 1 low-risk seismic area (Battelle, 1992).

Soils up to 6 ft thick have developed over the till. At least 9 ft of alluvium is present in the floodplain (Battelle, 1988). Soils in the area are predominantly silt loams in the Lewisburg-Celina-Miamian association at the West Jefferson site in Madison County (USDA, 1981) and in the Miamian-Celina and Kokomo-Crosby-Lewisburg associations immediately east of the proposed BL-3

laboratory site in Franklin County (USDA, 1980). All of the soils exhibit low permeability and all grade into till clay at depths of 55-60 inches; impermeability nearly precludes further percolation (Battelle, 1992).

4.1.2 AIR QUALITY/METEOROLOGY

Climate of the south-central Ohio region may be described as continental temperate. The region is subject to a wide seasonal range in temperature. Summers are quite warm; the mean temperature for the months of June, July, and August is about 73 degrees F. Temperatures of 90 degrees F or higher are expected about 15 days during these months while record high temperatures are 100-102 degrees F. The mean temperature for the months of December, January, and February is approximately 31 degrees F. Temperatures of 0 degrees F or less occur about 4 days per year while record low temperatures are in the -15 to -20 degrees F range (Battelle, 1992; NOAA, 1988).

Annual precipitation averages about 38 inches in the region and is distributed fairly uniformly throughout the year (Battelle, 1988) with the months of May-August having the highest precipitation means of about 4 inches.

Prevailing winds are from the southwest direction (Figure 4-1). In later spring and summer warm air mass inversions occur, resulting in frontal showers and thunderstorms. Occasionally, hot air mass thunderstorm development during, the late spring may be sufficiently strong to spawn tornado activity, particularly in the month of April; Cold fronts during the late fall, winter, and early spring, bring showers and thunderstorms (Battelle, 1992).

Air quality in the central Ohio area is generally within OEPA standards and National Ambient Air Quality Standards, except that the Metropolitan Columbus Air Quality Control Region is considered marginal for ozone (OEPA, 1989). Prevailing winds tend to transport metropolitan Columbus emissions away from the rural West Jefferson site (Battelle, 1992).

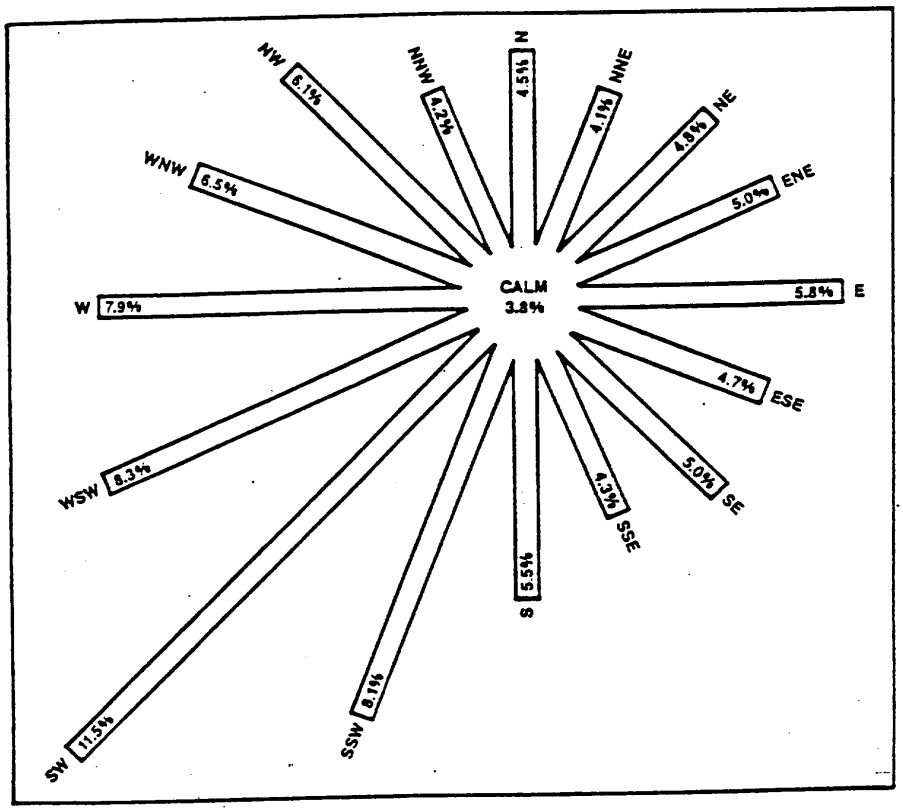

FIGURE 4-1. THE WIND PATTERNS AT BATTELLE'S WEST JEFFERSON COMPLEX ARE PREDOMINANTLY SOUTHWESTERLY

4.1.3 HYDROLOGY, WATER QUALITY, AND WATER USE

The principal surface hydrologic features at the site and in the immediate area are Big Darby Creek and Battelle Lake (see Figure 1-1). Battelle Lake, an impoundment oh Silver Ditch which flows into Big Darby Creek, has a nominal surface area of 25 ac (Battelle, 1992) and a volume of 275 ac-ft (Battelle, 1988). It is located approximately 550 ft north of the proposed BL-3 laboratory and is used primarily for recreational fishing by Battelle staff.

Big Darby Creek flows north-to-south and flows within about 500 ft east of the proposed BL-3 laboratory (see Figure 1-1). The only stream gauge is at Darbyville, about 40 river miles south and downstream of the site (Battelle, 1992). The average discharge over 65 years is 454 ft^3/sec (USGS, 1990). Flow varies widely from very low when the only perceptible flow is over riffles, to very high when the stream is in flood stage; the record low and high flows are 1.4 and 49,000 ft^3/sec, respectively. The stream gradient is quite low: about 0.8 ft/mi along the Battelle property boundary. Flow on Big Darby Creek varies considerably on an annual basis and over shorter periods. During dry weather the stream flow is due almost entirely to ground water. Flow increases rapidly during times of precipitation due to the low permeability of the till resulting in rapid runoff (Battelle, 1988). In the immediate vicinity of the proposed BL-3 laboratory, surface drainage to the north and west goes to Battelle Lake while drainage to the east and south goes into Big Darby Creek.

In general, Big Darby Creek has been reported to have excellent water quality (Battelle, 1975) and is classified as a State Natural Resource Water (Yoder, personal communication, 1992). The State Natural Resource Water designation means that no discharge can have pollutant concentrations greater than the ambient water quality. Water quality varies with flow conditions; during high-flow conditions, water quality generally improves, with the exception of suspended solids Data indicate that nutrient-rich agricultural runoff frequently enters the watercourse. The stream has low fecal coliform counts and high dissolved oxygen (Battelle, 1975). The only effluent discharged from

the West Jefferson facilities is the effluent from the sanitary sewage treatment system which is operated in accordance with State of Ohio regulations under NPDES Permit No 4NI00004*DD.

The water table in the area exists in the till between 2 to 10 ft below the land surface. The till has a very low hydraulic conductivity and can not be used as a source of water. The major aquifer is contained in the limestone/dolomite bedrock and it serves as a water supply source for the Battelle West Jefferson site and for much of the surrounding area (Battelle, 1988).

4.1.4 TERRESTRIAL ECOSYSTEMS

Extensive agriculture is practiced on much of the arable land at Battelle's West Jefferson site. The principal crops on the property are corn and soybeans (Battelle, 1992). Wooded areas predominate along the Big Darby Creek floodplain, along Battelle Lake, and on the steep slopes adjacent to the water bodies. Wetland areas also are present along the lake and creek edges. Dominant tree species include oaks, hickories, maples, ashes, basswood, sycamore, willow, and cottonwood. Herbaceous species include prairie remnant plant species along with grasses, asters, goldenrods, and spurges (Battelle, 1975).

Wildlife at Battelle's West Jefferson site include such game species as bobwhite, eastern cottontail, whitetail deer, red fox, fox squirrel, gray squirrel and wood duck. Examples of other types of animals are groundhogs, moles, mice, rats, chipmunks, hawks, owls, woodpeckers, nuthatches, wrens, frogs, snakes, and turtles (Battelle, 1975).

One terrestrial animal, the Indiana bat (*Myotis sodalis*), which is on both the Federal (50 CFR 17) and Ohio (OAC 1501: 31-23-01; ODNR, 1992) endangered species lists is believed to be present in the region. However, the Ohio Department of Natural Resources (ODNR) does not have any records for the Indiana bat in the vicinity of Battelle's West Jefferson Research site (Jones, personal communication, 1992).

Two species of birds included on the Ohio endangered species list (OAC 1501:31-2301; ODNR, 1992) may nest in the region (Pettyjohn and Rice, 1991); these are the American bittern (*Botarus lentiginosus*) and the loggerhead shrike (*Lanius ludovicianus*). Several other Ohio endangered species including the northern harrier (*Cirus cyaneus*), magnolia warbler (*Dendroica magnolia*) and dark-eyed junco (*Junco hyemalis*) may occasionally occur on the site as transients or winter residents (Pettyjohn, 1989; Pettyjohn and Rice, 1991) and others may occur from time to time.

4.1.5 AQUATIC ECOSYSTEMS

Big Darby Creek (see Figure 1-1) has one of the most diverse benthic and fish communities in Ohio (Battelle, 1975). Due to this high diversity of aquatic biota in Big Darby Creek, it is classed as an Exceptional Warm Water Habitat by the OEPA (Yoder, personal communication, 1992). This means that the OEPA can require more stringent chemical standards on discharges and effluents into the stream. The stream is populated by a large number of fish, insect larvae, mollusks, and other invertebrates that are indicators of good water quality.

Many species on Ohio's lists of threatened and endangered wildlife (ODNR, 1992) or rare native plants [Ohio Division of Natural Areas and Preserves (ODNAP), 1992) are found in Big Darby Creek, which borders Battelle's West Jefferson site. The following numbers of plant and animal species recorded for the entire Big Darby Creek have official status on Ohio lists: 11 endangered, 10 threatened, 9 special interest, and 7 potentially threatened (Jones, personal communication, 1992).

The Scioto madtom (*Notutus trautmani*), reported only from the lower fourth of Big Darby Creek, is on both the Federal (50 CFR 17) and Ohio (OAC 1501:31-23-01; ODNR, 1992) endangered species lists. Other fish species found in the lower portion of Big Darby Creek that are on the Ohio endangered species list are the northern brook lamprey (*Ichthyomyzon fossor*), northern madtom (*Noturus stigmosus*), and spotted darter (*Etheostoma maculatum*) (Jones, personal communication, 1992).

Mollusk species found in the Big Darby Creek adjacent to Battelle's property that are on Ohio's endangered species list (ODNR, 1992) include the clubshell (*Pleurobema clava*), the rabbitsfoot (*Quadrula cylindrica cylindrica*), and the northern riffleshell (*Epioblasma torulosa rangiana*). The northern riffleshell and the clubshell have recently been added to the Federal list of threatened and endangered species. Two mollusk species that have been found in Big Darby Creek adjacent to Battelle's property that are considered species of special concern by the State of Ohio are the wavy-rayed lampmussel (*Lampsilis fasciola)* and the round pig-toe (*Pleurobema sintoxia*). One additional mollusk, the snuffbox (*Epiblasma triquetra*), has been found in Big Darby Creek adjacent to Battelle's property and is considered a threatened species by the State of Ohio. (Jones, personal communication, 1993)

Battelle Lake contains populations of stocked or natural largemouth bass, channel catfish, bluegill and other sunfish, yellow perch, black crappie, chain pickerel, and others.

4.2 MAN-MADE ENVIRONMENT

The man-made environment discussed in this section includes land use, socioeconomics, demography, cultural and historical resources, transportation, and utilities and safety services.

4.2.1 LAND USE

Battelle's West Jefferson research site is located approximately 17 miles west of Battelle's King Avenue Facility in Columbus, Ohio. Managed by Battelle Columbus Operations, it is part of a 1,184-ac tract which accommodates three groups of research buildings: the North Area, Middle Area, and South Area. The proposed BL-3 laboratory will be located in the Middle Area. Approximately 750 ac of land in the central area are leased-to farmers. Soybeans and corn are generally cultivated in this area. The area immediately surrounding West Jefferson has low population density. A Girl Scout camp, Camp Ken-Jockety, is located on a bluff on the east side of Big Darby Creek (Figure 4-2). Several tent platforms and a unit kitchen are in the

southwestern portion of their property (McCormick, personal communication, 1992). Directly to the east of the site, across Big Darby Creek, there is a large residential subdivision called Lake Darby Estates.

4.2.2 SOCIOECONOMICS

The median age of the 1990 population in Jefferson Township (Madison County) was 33.7 years, with 11 percent 65 years or older. Median income for families was $35,790 (1989 dollars) in Jefferson Township. In 1990, Jefferson Township had 6.3 percent of its population below the poverty level, the median housing value for owner-occupied units was $63,200, and the average household size was 2.83 persons per household (Ohio Data Users Center, 1992).

The median age of the 1990 population in Prairie Township (Franklin County) was 32.0 years, with 7.4 percent 65 years or older. Median income for families was $36,830 (1989 dollars) in Prairie Township. In 1990, Prairie Township had 7.4 percent of its population below the poverty level, the median housing value for owner-occupied units was $63,800, and the average household size was 2.85 persons per household (Ohio Data Users Center, 1992). Madison County has increased its total employment base from 4,984 in 1980 to 6,686 in 1989 (U.S. Department of Commerce, 1982 and 1991). However, manufacturing activity in the County declined slightly from 1,495 employees in 1980 to 1,470 in 1989, while the retail trade grew from 1,354 persons in 1980 to 2,057 in 1989 and service employment grew from 929 persons in 1980 to 1,380 in 1989. The major manufacturing plants in West Jefferson are Capitol Manufacturing and Jefferson Industries.

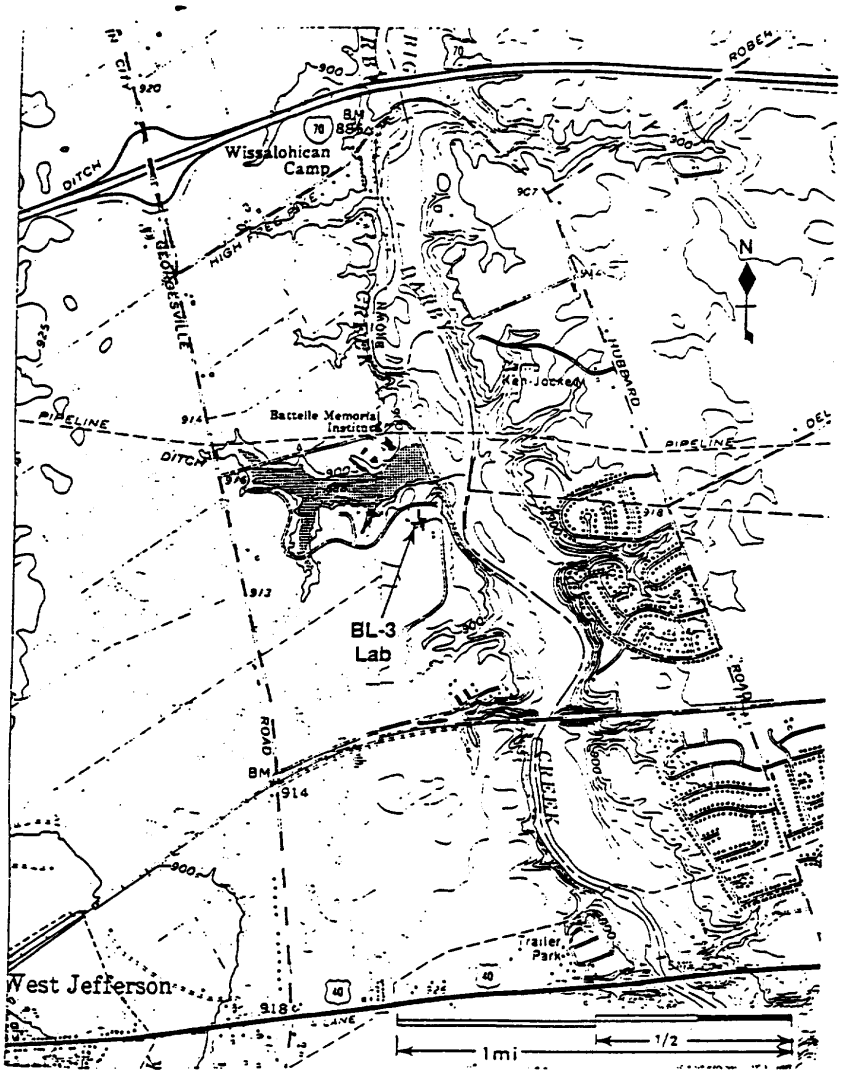

FIGURE 4-2. RESIDENTIAL DEVELOPMENT AND TRANSPORTATION ROUTES IN THE IMMEDIATE VICINITY OF THE PROPOSED BL-3 LABORATORY

4.2.3 DEMOGRAPHY

Battelle's West Jefferson site is located in a rural environment characterized by farmland and several nearby completed and developing residential subdivisions. The population in the area has been stable with Jefferson Township (Madison County) showing a small decrease and Prairie Township (Franklin County) showing a small increase. Jefferson Township's population decreased from 7,055 in 1980 to 6,987 in 1990 (Ohio Data User's Center, 1992). Prairie Township population increased from 16,340 in 1980 to 16,945 in 1990 (Ohio Data User's Center, 1992).

The village of West Jefferson, which is about 2 miles southwest of the site (see Figure 4-2), had a population of 4,448 in 1980. The village population was 4,505 in 1990 (Ohio Data User's Center, 1992).

Subdivision development in areas such as Lake Darby Estates has experienced continued growth since 1980. Lake Darby Estates is serviced by the Ohio Utilities Company. They currently serve 770 residential customers (Ohio Utilities Company, 1990). Use of the average household size multiplier of 2.83 persons per household for Prairie Township (Ohio Data User's Center, 1992) would suggest that the estimated population for Lake Darby Estates is about 2,180.

Camp Ken-Jockety operates a day camp during the summer months (mid-June to early-August) with about 100 persons present on week days. On summer weekends, the camp generally is used only for special programs. During the winter, the camp's three lodges are used extensively on weekends by an approximate average of 60 people. In addition, after-school programs are held two afternoons per week with approximately 80 persons. Occasionally, school groups visit the camp for field trips. The camp is also planning to construct an environmental center. Groundbreaking was in the fall of 1992; however, actual completion date is uncertain.

A staff of approximately 135 are employed at Battelle's West Jefferson facilities. The majority of these individuals are residents of either Madison or Franklin counties. Up to eight additional staff members may be added for the proposed BL-3 laboratory. Additionally, some staff assigned to Battelle's King Avenue site frequently work in some of the West Jefferson facilities.

4.2.4 CULTURAL AND HISTORICAL RESOURCES

Big Darby Creek flows along the east boundary of Battelle's West Jefferson site, and at one point is about 500 ft east of the proposed BL-3 laboratory. The creek is listed as an Ohio Scenic River by the ODNAP, and is currently under consideration by the National Park Service for inclusion on the National Scenic Rivers list (Kopec, personal communication, 1993). It is likely that the Big Darby Creek will be listed as a National Scenic River sometime during 1993.

The Skunk Hill Mound group, which is South of West Jefferson, is the only listed National Register of Historic Places property in Madison County that is in the vicinity of the proposed BL-3 laboratory (Rau, personal communication, 1992). No formal surveys for cultural and historic resources have been conducted on Battelle property, although none of these resources are expected.

As part of the scenic river protection program, ODNR owns a 7.16 ac tract of land along the west bank of Big Darby Creek north of the Battelle West Jefferson site near Interstate 70. There are no other state-protected lands within a 1-mile radius of the proposed BL-3 laboratory (Moseley, personal communication, 1990).

4.2.5 TRANSPORTATION

Battelle's West Jefferson research site is readily accessible to interstate, U.S., and state highways. The site is bordered on the west by State Route 142 (Plain City-Georgesville Road) (see Figure 4-2). Access to and egress from the site is provided by a paved service road connecting the site with State

Route 142 at two locations. Interstate 70 is approximately 1 mile north of the site, and U.S. Highway 40 is approximately 1 mile to the south. Although the site is bordered on the south by Conrail railroad tracks, there is no spur connecting the site to the Conrail railroad tracks.

Roadways in the vicinity are not congested or restricted. There are no inordinate hazards or restrictions, such as steep grades, sharp turns, load limits, or height restrictions, between the site and Interstate 70. The site service road is fully paved and does not present any hazards or restrictions for truck or automobile activity.

4.2.6 UTILITIES AND EMERGENCY SERVICES

Battelle's West Jefferson research facilities receive electricity at 4,160 v from the Battelle West Jefferson substation, located on site. The Ohio Power Company is the electrical service provider. Current plans provide two boilers to generate steam for use in the proposed BL-3 laboratory for heating, humidifying, and sterilization. Generally, one will be used as the primary unit with the other acting as backup. Occasionally, demand may be such that more than one unit will operate simultaneously. Facility cooling is achieved using electric, motor-driven chillers.

Initial emergency-response services at the proposed BL-3 laboratory will be provided by Battelle on-site staff. Guards are based at the south area guard station, and a nurse trained in acute treatment of toxic material exposures is located at the middle site. The nurse will receive additional specialized training in treatment of toxin exposures before operation of the BL-3 laboratory begins. If Battelle security and/or medical personnel have evaluated an emergency situation and have determined that additional assistance is necessary, they contact the police, fire, and/or emergency medical services provided by the town of West Jefferson and Jefferson Township (see also Section 2.3 on the proposed BL-3 laboratory security, including guards). The nearest emergency medical care facilities are The Ohio State University Hospital and Doctor's West Hospital. Formal emergency support arrangements with these agencies will be in place prior to operation of the laboratory.

The Jefferson Township fire Department serves Fairfield and Jefferson Townships. They have 10 full-time, and 30 part-time firefighters. The Jefferson Township Fire Department Emergency Squad includes two medic-equipped vehicles (Hockenbery, personal communication, 1992). The Village of West Jefferson has 8 full-time, 4 part-time, and 11 auxiliary police officers (Hunter, personal communication, 1992).

4.3 LITERATURE CITED

Battelle Columbus Division, 1975. An Environmental and Ecological Assessment of the Proposed Upper Darby Water Supply Project. Prepared for Burgess and Niple, Ltd., Columbus, OH. June.

Battelle, 1988. Data Compilation and Draft Summary of the Geological and Hydrological Conditions at the West Jefferson Site Battelle Memorial Institute. Internal Draft Report. Columbus, OH. 6 September.

Battelle, 1992. Site Environmental Report For Calendar Year 1991 on BCLDP 10192. U.S. Department of Energy, DOE Field Office, Chicago, IL. 1 October.

Hockenbery, M., 1992. Telephone conversation with L.A. Smith, Battelle. Jefferson Township Fire Department. 15 September.

Hunter, M., 1992. Telephone conversation with L.A. Smith, Battelle. West Jefferson Mayor's Office. 15 September.

Jones, P., 1992. Telephone conversation with D.A. Tolle, Battelle. Follow-up letter contained computerized list of natural heritage elements recorded for Big Darby Creek (dated 5 March 1992). Manager of Endangered Species Data Base, Division of Natural Areas and Preserves, Ohio Department of Natural Resources. 11 and 14 September.

Jones, P., 1993. Telephone conversation with P. Gorman, Battelle. Manager of Endangered Species Data Base, Division of Natural Areas and Preserves, Ohio Department of Natural Resources. 7 April.

Kopec, J., 1993. Telephone conversation with D.A. Tolle, Battelle. Division of Natural Areas and Preserves, Ohio Department of Natural Resources. 11 January.

McCormick, M., 1992. Telephone conversation with S.E. Brauning, Battelle. Seal of Ohio Girl Scout Council. 4 September.

Moseley, R., 1990. Telephone conversation with S.E. Brauning, Battelle. Director, Division of Natural Areas and Preserves, Ohio Department of Natural Resources. 21 August.

National Oceanic and Atmospheric Administration, 1988. Local Climatological Data--1987 Annual Summary with Comparative Data--Columbus, Ohio. National Climatic Data Center, Asheville, NC.

Ohio Administrative Code 1501:31-23-01. Special Endangered Wild Animal Regulations. (1991)

Ohio Data User's Center, 1992. Telephone conversation between L.A. Smith, Battelle, and G. Rohas, ODUC, 9 September.

Ohio Department of Natural Resources (ODNR), 1992. Species of Animals that are Considered to be Endangered, Threatened, of Special Interest, Extirpated, or Extinct in Ohio. Inservice Note 659. Division of Wildlife, ODNR, Columbus, OH. May 1992.

Ohio Division of Natural Areas and Preserves (ODNAP), 1992. Rare Native Ohio Plants: 1992-1993 Status List. ODNR, Columbus, OH.

Ohio Environmental Protection Agency (OEPA), 1989. Ohio Air Quality Report, 1989. Ohio Environmental Protection Agency, Columbus, OH.

Ohio Utilities Company, 1990. Correspondence to R. Hines: Number of Residential Customers at Lake Darby Estates. 22 February.

Pettyjohn, B.G., 1989. The Birds of Ohio. Indiana Univ. Press. 256p.

Pettyjohn, B.G., and D.L. Rice, 1991. The Ohio Breeding Bird Atlas. Ohio Department of Natural Resources, Columbus, OH.

Ray, J., 1992. Telephone conversation with L.A. Smith, Battelle. Ohio Historic Preservation Officer, Ohio Historical Society, 15 September.

U.S. Department of Agriculture, 1980. Soil Survey of Franklin County. Ohio. Soil Conservation Service, Columbus, OH. February.

U.S. Department of Agriculture, 1981. Soil Survey of Madison County, Ohio. Soil Conservation Service, Columbus, OH. June.

U.S. Department of Commerce, 1982. County Business Patterns 1989 - Ohio, CBP-89-37. Washington, D.C.

U.S. Department of Commerce, 1991. County Business Patterns 1989 - Ohio, CBP-89-37. Washington, D.C.

U.S. Geological Survey, 1990. Streamflow: Station 03230500 Big Darby Creek at Darbyville OH. Scioto River Basin--1989.

Yoder, C., 1992. Telephone call with D.A. Tolle, Battelle. Manager, Ecological Assessment Section, Ohio Environmental Protection Agency. 14 September.

50 CFR Part 17. Endangered and Threatened Wildlife and Plants. (1991)

5.0 ENVIRONMENTAL CONSEQUENCES OF PROPOSED ACTION AND ALTERNATIVES

This section describes the most significant direct and indirect environmental and socioeconomic consequences that could reasonably be expected to occur as a result of the proposed action to establish and operate a BL-3 laboratory for evaluating the efficacy of medical countermeasures against toxin threats. This evaluation includes the selection and definition of a maximum credible event (MCE) and evaluation of potential direct effects of the MCE on human health and biota. A rationale is included for selection of a "safe" dose, or maximum permissible dose (MPD), which is used to evaluate the impact of the MCE on human health.

Normal operations at the proposed BL-3 laboratory are not expected to result in any release of toxins to the environment due to the design of the facilities and the elaborate safety procedures in place for handling toxins (see Section 2.3). Therefore, the impacts discussed in this section are based on the highly unlikely event of an accident with sufficient severity to cause release of toxins to the environment. Description of the MCE selected, as well as accidents considered less serious or incredible, are discussed in the following paragraphs.

5.1 DEFINITION AND DESCRIPTION OF THE MAXIMUM CREDIBLE EVENT

One major concern regarding the potential environmental impacts of the proposed action is the accidental release of toxins. Selection and analysis of a MCE scenario is one method to respond to public interest regarding what might happen if an unexpected, but possible, accident event should occur. The MCE is a realistic event that has some probability of occurrence and would result in the maximum potential consequences. Evaluation of the MCE is required by 32 CFR Part 627 (57 FR 11368) as part of the safety program for biological defense RDT&E operations involving etiologic agents and is frequently used for impact analysis in an EA.

The three toxins currently planned for use in the laboratory are botulinum toxin, ricin, and staphylococcal enterotoxin B. Of these, or any other toxin which potentially may be used in the BL-3 laboratory, botulinum toxin is the most toxic (USAMRDC, 1989; Joklik, et al., 1988) so it serves as the basis for the MCE calculations. Botulinum toxin is an exotoxin of *Clostridium botulinum*, a common soil pathogen. This extremely potent toxin is most familiar to the general public as the causative agent of botulinum food poisoning, notably from canned seafoods and low acid vegetables.

The MCE for this EA is selected based on an evaluation of the activities planned for the laboratory and the design and administrative control features. The postulated mechanism for the largest credible potential exposure of the public is release of the entire amount of toxin used for one test into the interior of a Class III cabinet followed by release of the toxin through the cabinet filtration system.

During a normal test operation, a fixed quantity of toxin is administered as an aerosol. The aerosol is generated by a nebulizer system in a Class III cabinet during the course of a test. Only the quantity of toxin required for the test is in the cabinet and available for aerosolization.

The aerosolized toxin is administered through a tubing system. Normally any by-passed toxin aerosol is transferred by tubing into a decontamination solution. The aerosol is discharged into the solution through a bubbler tube or fritted bubbler to ensure good contact of the toxin and the solution. Should the discharge line or bubbler become occluded and the pressure regulator fail, the aerosolized toxin would enter the internal volume of the Class III cabinet.

Determination of the MCE involving a release of botulinum A toxin initially requires calculation of the maximum quantity of aerosolized botulinum A toxin expected to be present in a Class III cabinet for a single experiment involving an aerosolized challenge of experimental animals. Thus, information on the maximum challenge dose was solicited from MBDRP personnel, and this was reported to be 1.2 ng/kg. It was assumed that the test involved anesthetized

animals which were exposed to toxin via the respiratory route using a head only enclosure, and that these animals weighed a total of 14 kg. An airway deposition efficiency of 30 percent was conservatively estimated, and a 16 fold excess flow of dose aerosol to permit measurements and aerosol sampling was selected.

$$\frac{(1.2 \text{ ng/kg} \times 14 \text{ kg}) \times 16 \text{ fold excess}}{0.30 \text{ deposition efficiency}} = 896 \text{ ng}$$

The above calculations result in an estimated quantity of botulinum A of 896 ng, or approximately 1 μg. To allow maximally for any future changes in test parameters which might be requested, a factor of 10 was used to increase this amount of toxin to 10 μg, or 0.01 mg.

The MCE resulting from release of an aerosol of toxin into a Class III cabinet is controlled by the maximum amount of toxin available during the test and the efficiency of the cabinet filtration. As indicated above, the maximum expected quantity of toxin to be used in any test is 0.01 mg. If the release occurs at the beginning of the test and the test is not terminated, the entire mass of toxin could enter the cabinet as an aerosol. The blower system would exhaust the cabinet through two HEPA filters in series. Each filter would remove 99.97 percent of the aerosol. Therefore, total release at the laboratory ventilation discharge is (1-0.9997) (1-0.9997) (0.01 mg) or 0.9 pg. The duration of the atomization release process is expected to be about 5 to 10 minutes.

5.2 ACCIDENTS CONSIDERED BUT NOT USED AS THE MAXIMUM CREDIBLE EVENT

Accidents considered, but not used as the MCE, included the following three categories: potential accidents with lower release, potential accidents with no release of toxins, and events that are not considered credible. Each of these accident categories are summarized below.

5.2.1 POTENTIAL ACCIDENTS WITH LOWER RELEASE

5.2.1.1 Spill of Material During Preparation

Toxin could be spilled in a Class III Biological Safety Cabinet during dose preparation or material handling. The total quantity of toxic material will typically be larger than during the dose administration. However, during dose preparation and materials handling activities, the toxins are not present as aerosols. The amount of aerosol generated by a spill or similar accident is reported to be less than 0.04 percent of the total material spilled (USAMRDC, 1989). Therefore, despite the potential for a larger amount of toxin spilled, the aerosol challenge to the filtration system is smaller.

5.2.2 POTENTIAL ACCIDENTS WITH NO RELEASE OF TOXINS

5.2.2.1 Handling Accident Outside of a Containment Area

Material will be received from the supplier in shipping packages and overpacks that meet or exceed DOT requirements. Unpacking of primary material containers, handling of material in open containers, and dose preparation will occur only in Class III containment cabinets. Material transfers within the laboratory, outside of Class I, Class II and Class III containment, will require material to be packaged to meet or exceed DOT requirements. Should an accident occur during transfers, the packaging will prevent release of material. Therefore, a release of toxic material outside of a containment cabinet is not considered credible.

5.2.2.2 Tornado Damage

All material is returned to a tornado-proof vault in the event of a tornado warning. Use of toxins is not allowed during any period when a tornado warning is in force for the area around the laboratory. Therefore, it is not credible to expect material to be released in the event of tornado damage to the laboratory.

5.2.2.3 Fire

Should a major fire occur and remain uncontrolled long enough to compromise laboratory containment, the intense heat would destroy any toxins planned for use in the laboratory. Therefore, it is not credible to expect a laboratory fire to result in release of material.

5.2.2.4 Explosion

The only potential source of explosion is the natural gas supply to the laboratory boiler/utilities. The boiler area will be distant and isolated from any areas containing toxins and equipped with a wall designed to vent the pressure away from the laboratory. Should a gas explosion occur, damage would not compromise toxin containment systems. Therefore, it is not credible to expect an explosion to result in release of material.

5.2.3 EVENTS THAT ARE NOT CONSIDERED CREDIBLE

5.2.3.1 Loss of Laboratory Ventilation Control

Since failure of the exhaust system could be a major health concern in the laboratory, the exhaust system is provided with redundant systems to ensure continued operation in all credible events (see Section 2.3.7.5). Redundant blowers allow continued ventilation system operation in the event of a blower failure. To ensure that power is always available to these blowers, a battery-based uninterruptible power supply system, backed up by a diesel generator, is available for blower operation in the event of off-site power failure. Failure of redundant ventilation systems is not considered credible.

5.2.3.2 Airplane Crash

The West Jefferson site is more than nine miles from the nearest public airport and is not in the approach/departure path of any airport. Therefore, an airplane crash is not considered a credible mechanism for toxin release.

5.2.3.3 Earthquake

The West Jefferson-site is in a Zone 1, low-risk seismic area (see Section 4.1.1). Therefore, the occurrence of an earthquake of sufficient intensity to cause release of toxins to the environment is not considered credible.

5.2.3.4 Flooding

The West Jefferson site is located on bluffs which are far above the 100-year flood plain of the Big Darby Creek and the Battelle Lake. Therefore, flooding is not considered a credible mechanism for toxin release.

5.3 RATIONALE FOR A MAXIMUM PERMISSIBLE DOSE FOR BOTULINUM A TOXIN

In order to evaluate the impact of an MCE involving release of botulinum A toxin on human health, it is first necessary to estimate a "safe" dose, or a maximum permissible dose (MPD), a dose which would not cause deleterious effects. Since requirements for experiments at the proposed BL-3 laboratory necessitate the formation of toxin aerosols in order to validate the efficacy of candidate toxoids, there exists the possibility, however unlikely, of releasing toxin in a respirable form into the environment. Because of the manner in which experiments are to be performed, the most probable of improbable scenarios would be a single, very short-term, inhalation exposure.

Clostridium botulinum, a gram-positive, anaerobic, spore-forming, rod-shaped bacteria produces botulinum, which is the most potent exotoxin known (Joklik, et al., 1988). There are eight serologically distinct botulinum toxins, designated A, B, C_1, C_2, D, E, F. and G, with A being the most toxic. Botulism received its name from the Latin *botulus* (sausage), and is a term introduced in 1870 to describe a food-poisoning syndrome associated with the eating of sausage (Joklik et al., 1988; Sakaguchi, 1983). Botulinum is not just an ingestion-hazard, as botulism can also result from contaminated wounds or inhalation of the toxin (Joklik et al., 1988; Holzer, 1962).

Signs and symptoms of intoxication include blurred vision, double vision (diplopia), difficulty in speaking (dysphonia), and generalized weakness (Saving and Maus, 1991). Decreased cholinergic autonomic transmission results in dry mouth and eyes, urinary retention, nausea, and vomiting. The mechanism of action is a blocking of the release of the neurotransmitter acetylcholine (ACh) at cholinergic nerve terminals (Kao et al., 1976; Scott, 1981). This is not related to Ca influx or the reduction of ACh stored in synaptic vesicles, but rather to irreversible failure of synaptic vesicle exocytosis. Recovery of innervation is associated with the sprouting of new nerve terminals (NIH, 199O). The toxin does not appear to penetrate the blood brain barrier and act centrally, nor does the toxin appear to have an effect upon the heart since the rhythmicity of the heart is not dependent upon cholinergic innervation (Scott, 1981). Botulinum toxin has high affinity for nerve endings in skeletal muscle, and the probable cause of death in fatal cases is respiratory arrest due to functional denervation and subsequent failure of the respiratory muscles (Sugiyama, 1980; Lamanna and Carr, 1967).

Despite the toxicity, of botulinum toxin, it has been used safely and effectively in the treatment of specific muscular disorders in man. The neuromuscular blocking action of botulinum A has been used to alleviate muscle spasm due to excessive neural activity of central origin or to weaken a muscle for therapeutic purposes (Savino and Maus, 1991; Scott, 1981; NIH, 1990). Local injections of botulinum A are effective in the treatment of deviation of an eye (strabismus), tonic spasms of the muscle surrounding the eye (blepharospasm), and hemifacial spasm. The FDA has approved injection of toxin for these conditions (Scott, 1981; NIH, 1990). Side effects are generally transitory, well tolerated, and amenable to treatment. Persistent complications are rare and serious side effects are uncommon. Doses of 5 to 60 IU are commonly injected to denervate a muscle for weeks to months (Savino and Maus, 1991). Doses of 200 IU have been used in man for treating contracted cervical muscles which produce a twisting of the neck (torticollis) (Truong, 1991).

Because of its extreme toxicity, the most commonly used method of detection and quantification of botulinum toxin is the mouse toxicity and neutralization test (Joklik et al., 1988). An enzyme-linked immunosorbent assay (ELISA) has been developed, but, at present, is not as sensitive as the mouse method. The mouse test determines the quantity of toxin which, when injected intraperitoneally (IP) into female Swiss Webster mice, will kill 50 percent of the mice (median lethal dose; MLD) (Savino and Maus, 1991). One international unit (IU) of botulinum A toxin is defined as the mouse MLD. The mouse IP MLD has been estimated by a number of investigators, and ranges from 3.2 to 26 pg (Sigma Chemical Company, 1991; Joklik et al., 1988; Lamanna, 1959; Gill, 1982). The differences in these MLD estimates probably result from statistical variations in the data due to both procedural variables and biological variability in the animal model.

The route of exposure to botulinum has an effect on what is considered a “safe” dose. While lethal doses by the intravenous, intraperitoneal, intramuscular, and subcutaneous injection routes are approximately the same and reach essentially equivalent blood levels but at various times, the toxin is less potent by the respiratory route, and is least potent by two or more orders of magnitude by the oral route (Lamanna and Carr, 1967). This corresponds to what one could predict due to relative resistance to passage of protein across tissue barriers per unit area (Scott, 1981; Lamanna, 1959). The toxic dosages of botulinum toxin are very different when comparing human toxin aerosol exposures with mouse IP toxin solution challenges. Besides species differences, not all aerosolized toxin is inhaled, and not all inspired toxin is retained in the lungs, nor, as mentioned above, is all toxin absorbed into the blood stream from the lungs.

For human beings, there are widely different estimates of the amount of toxin required to induce botulism or to cause death (Scott, 1981). The parenteral MLD for botulinum A in man has been estimated at 44 ng (Gill, 1982) to 1 to 2 μg (Sigma Chemical Company, 1991; Scott, 1981). As expected with a potent toxin, the dose-response curve for botulinum is very steep. From data presented by Gill (1982), the slope of the botulinum A dose-lethal response has been estimated at approximately 20. Therefore, even though a toxic or

lethal dose may be very low, a non-toxic dose will not be much lower than a toxic one. The parenteral dose that would kill essentially all human beings injected with that amount has been estimated at 1 ng/kg, or 70 ng for a 70 kg "standard man" (Gill, 1982). Assuming a slope of the toxin dose-human lethal response curve of approximately 20, a human parenteral MLD of 44 ng can be calculated, and a calculated dose that would not produce any lethality is 27 ng. Ignoring the effects of route of exposure, ignoring the fact that therapeutic doses as high as 200 IU (640 pg if the lowest cited mouse IP MLD is used to determine the IU) are injected intramuscularly, and assuming a no-effect dose of 10 ng, and applying a safety factor of 1000, 10 pg would be a very conservative estimate of a human MPD, a dose not expected to cause any discernible effect following exposure.

5.4 DIRECT EFFECTS OF MCE ACCIDENT ON HUMAN HEALTH AND BIOTA

In the extremely unlikely event of an MCE accident at the proposed BL-3 laboratory (see Section 5.1), the minute quantity of toxin that could be released from the stack, even before dilution in the ambient air, is not sufficient to cause any effect on human health or biota. The rationale for this conclusion is discussed in the following two subsections.

5.4.1 EFFECTS Of MCE ON HUMAN HEALTH

No effect on human health or the public are expected to result from the occurrence of the MCE accident, because the quantity of toxin estimated to be released by the MCE is extremely low (0.9 pg - see Section 5.1). This amount is less than the estimated MPD of 10 pg,. the dose calculated to be safe for human exposure (see Section 5.3). The quantity of the release is a conservatively high estimate, since it is the total amount that would be released at the facility ventilation discharge point without considering any dispersion that would occur once the toxin was released into the atmosphere. Also, the MPD has been conservatively calculated since it is 1000 times lower an estimated no-effect dose.

As noted previously in this document, there is no risk of infection or multiplication of organisms from the proposed activity because the toxins are purified extracts from the living organisms and cannot replicate. Only extracted toxins provided by the DA or purchased from commercial sources will be used.

The safety features of the laboratory will minimize any exposure of workers to the toxins, even if the MCE were to occur. The laboratory will be designed and operated to meet the biocontainment criteria for BL-3. Safety features include engineering controls, protective equipment, operating procedures, and training of personnel as discussed in detail in Section 2.3. Generation of the aerosol in the case of the MCE would be conducted in a Class III biological cabinet. These cabinets are totally sealed and under negative pressure, and vented through two HEPA filters. Activities are conducted using rubber gloves attached to the biological cabinet, so that workers should not be exposed. Workers will be wearing protective clothing, such as disposable coveralls, hair bonnet, booties, surgical gloves. When inside the BL-3 post exposure area of the proposed laboratory, a HEPA-filtered respirator will be used for further protection. In some cases, when efficacious toxoids are available and recommended by Battelle medical staff, workers will be immunized for additional protection. A pentavalent toxoid is available for botulinum toxins Types A-E, and will be given to workers prior to initiation of experiments with this toxin.

5.4.2 EFFECTS OF MCE ON BIOTA

Botulism epizootics are known to occur naturally in the wild, especially in waterfowl, but this type of disease outbreak could not be caused by any accidental release of toxin from the proposed BL-3 laboratory. Of all the diseases that affect waterfowl, the one causing the most massive and visible losses is botulism (Bellrose, 1976; Jensen and Williams, 1964). The specific strain of neurotoxin usually attributed to these waterfowl deaths is botulinum Type C. Although the disease is most prevalent in the western parts of the U.S., particularly Utah and California, botulism has also been reported in states east of the Mississippi River. Botulinum bacteria develop when high

temperatures cause spores to germinate at the same time that there is suitable nutrient medium and an environment devoid of oxygen. Studies in California (Hunter et al., 1970) suggest that aquatic invertebrate carcasses and maggots feeding on dead waterfowl may serve as both a substrate (microenvironment) for botulinum Type C toxin production and as a vehicle for toxin transmission to water birds. However, studies by Moulton et al. (1976) indicate that this microenvironment concept is not always sufficient to explain how Type C epizootics are initiated in nature. Other microbes may inhibit the growth of clostridial bacteria or destroy botulinum toxin.

Due to the extremely small quantity (0.9 pg.) of botulinum A toxin released from the stack of the proposed BL-3 laboratory in the unlikely event of a MCE accident, it is not expected to have any impact on biota in the vicinity. The total amount of botulinum A toxin released during the hypothetical MCE before dilution in the air is far below the mouse IP MLD of 3.2 pg (Sigma Chemical Company, 1991). Within a few inches of the stack, this amount of toxin would undergo extreme dilution in the atmosphere and the toxin itself would rapidly undergo physical degradation. It is important to note that since toxins which have been extracted from microorganisms are proposed for study in the BL-3 laboratory, no live bacteria could be released during an MCE. Thus, the toxin can only degrade in the environment, and no additional toxin, due to cellular metabolism, can be produced.

Even if a hypothetical MCE accident involved the release of Type C toxin, instead of Type A toxin, into the environment, no impact on waterfowl or other biota is likely. Since the amount of botulinum toxin released in an MCE would be of the same relative toxicity regardless of the botulinum type, the amount of toxin released would be far below the IP MLD for the mouse, as well as other species of birds and mammals. Although most of the toxicity data available for animals is based on exposures administered by injection or orally, Lamanna and Carr (1967) have reported that the toxin is less potent by approximately an order of magnitude by the respiratory route, and is least potent by two or more orders of magnitude by the oral route. Also, information in a literature review on botulinum food poisoning by Riemann (1973) indicates that the oral lethal dose for a wide variety of birds and

mammals with a variety of botulism toxin types are always two or more orders of magnitude greater than the mouse lethal dose by injection. The MLDs reported by Gill (1982) for the various types of botulinum toxins in ng/kg of body weight ranges from 0.4-2.0 IP for the mouse, 0.1-0.6 IP for the guinea pig, 0.08-1.1 for the rabbit, and 1.1-40 for the monkey. Studies by Boroff and Reilly (1959) with the botulinum C_2 toxin have shown that an IM MLD dose for the pheasant or duck is equivalent to 50 and 500 times, respectively, the mouse IM MLD. They also found that one oral MLD for the mouse was equivalent to one MLD for a duck and 10 MLDs for a pheasant. The total amount of any type of botulinum toxin released in the unlikely event of an MCE accident, therefore, would be far below the MLD by injection for birds or mammals, and thus, even farther below the MLD for inhalation or ingestion.

5.5 INDIRECT EFFECTS AND OTHER NEPA REQUIREMENTS

This section discusses the potential for indirect effects, such as effects on socioeconomics or cultural resources, due to routine operation or a MCE accident at the proposed BL-3 laboratory. In addition, other evaluations specifically required by NEPA are addressed in this section, including land use conflicts, unavoidable adverse environmental effects, short-term use versus long-term productivity of the environment, irreversible and irretrievable commitment of resources, energy requirements and conservation potential, and mitigative measures.

5.5.1 SOCIOECONOMIC EFFECTS

Operation of the proposed BL-3 laboratory is not expected to adversely affect the local economy, public services, revenue generation, social structure, or behavioral patterns present in the area. In the event that a MCE resulted in the temporary suspension of research at the BL-3 laboratory, there would not be any significant impact on the local economy of Madison County. About eight persons will be assigned to the BL-3 laboratory. Some of these employees will be Madison County residents. Most of the purchases related to the operation of the laboratory will be made outside the county. Some of the purchases

related to the laboratory will be made in Madison County or nearby Franklin County, but these purchases will likely be an insignificant portion of the total operational cost of the laboratory.

Any credible accident would not be expected to have any direct impact on the health of neighboring landowners or the public-at-large (see Section 5.4). However, there could be some concerns that might arise from such an event which could indirectly affect future perceptions that people living in, camping in, or visiting the areas adjacent to Battelle would not be completely safe. If these unfounded fears about potential human health impacts occur and are not alleviated, it could result in lower land values, avoidance behavior, and other unnecessary reactions.

5.5.2 CULTURAL AND HISTORIC EFFECTS

There are no known historic or prehistoric resources near the proposed BL-3 laboratory or in close proximity to the Battelle property (see Section 4.2.4). The only cultural resource nearby is Big Darby Creek, which is about 500 ft east of the proposed BL-3 laboratory on the eastern border of Battelle's property. Big Darby Creek is listed as an Ohio Scenic River and is under consideration as a National Scenic River. Since the amount of toxin released during a MCE is far below levels considered toxic to biota, no adverse impact is expected on Big Darby Creek or any other historic or cultural resources located farther off site.

5.5.3 LAND USE CONFLICTS

Land use conflicts are not expected to result from operations at the proposed BL-3 laboratory. The outer shell of the building (JM-1) was built for another purpose on an existing site owned by Battelle. The shell will be renovated and modified for use as the BL-3 laboratory Activities at the proposed laboratory are research oriented, and thus, will be consistent with other activities at the West Jefferson site. The zoning designation for the site

includes research and testing among the uses allowed without special approval. There are no land use plans currently in effect for Madison County (Ames, 1992; Hastings, 1992).

5.5.4 UNAVOIDABLE ADVERSE ENVIRONMENTAL EFFECTS

Under normal operation of the proposed BL-3 laboratory, no significant unavoidable environmental effects have been identified. Even in the event of an accident resulting in release of toxin, the maximum quantity released is not expected to cause any negative impact. Evaluation of the MCE accident indicates that the total amount (0.9 pg) of botulinum A toxin released from the stack over a 5-10 minute period will be far below the dose (10 pg) considered safe for human inhalation exposure without even considering the additional dilution that would occur after mixing with ambient air. Therefore, the only potential hazard would be to workers inside the laboratory. Again, this is not expected to occur and extensive safety precautions have been taken to prevent an accident from occurring and to minimize the severity if an accident did occur. Workers will receive extensive safety training, will wear HEPA-filtered respirators, will be inoculated with a vaccine for botulism, and will be prepared to respond in the unlikely event of an accident.

With respect to effects to the natural environment, no significant impact is expected. The proposed BL-3 laboratory will be constructed on an existing site, and therefore no natural areas will be disturbed. Air emissions will be maintained in compliance with regulatory limits set forth in the air permit and the water effluents will be tested and maintained within the limits set forth in the NPDES permit.

5.5.5 SHORT-TERM USE VERSUS LONG-TERM PRODUCTIVITY OF THE ENVIRONMENT

The short-term use of the proposed BL-3 laboratory is for the purpose of evaluating the efficacy of candidate medical countermeasures in preventing the

effects of toxins that could be used in BW. Since there is no significant long-term impact anticipated to result from the laboratory, the short-term use is acceptable.

5.5.6 IRREVERSIBLE AND IRRETRIEVABLE COMMITMENT OF RESOURCES

No irreversible effects are anticipated from normal operations of the proposed BL-3 laboratory. Research at the BL-3 laboratory requires use of some non-renewable resources. These resources include energy resources (see Section 5.5.7 below) used to operate the laboratory, laboratory materials, chemicals, and other items such as disposable protective clothing, air filters, etc. These resources are necessary for the safe operation of the laboratory.

5.5.7 ENERGY REQUIREMENTS AND CONSERVATION POTENTIAL

Energy requirements for operation of the proposed BL-3 laboratory are expected to be high. Based on engineering design calculations for renovation of Building JM-1 and the equipment required for the BL-3 laboratory, annual energy use for the BL-3 laboratory is expected to be approximately 1,104,000 kWh of electricity for cooling, lighting, and equipment, and 5.431 mcf of natural gas for heating. The primary cause of the elevated energy use is the single pass-through ventilation system. This type of ventilation is required for safety in the event that a toxin is released in a biological safety cabinet; however, it is inefficient in terms of energy requirements. Use of a heat exchange mechanism to recover some of the lost energy is not feasible for the BL-3 laboratory due to the extensive filtration system that the air must pass through before being exhausted.

The laboratory will attempt to conserve energy where feasible. The biological safety cabinets used in research are a significant energy drain when open and in operation due to the high air flow. To conserve energy, biological safety cabinets are closed at the end of the day unless a particular research activity requires that they be left open. Lights are turned off at the end of the day when the laboratory is closed.

5.5.8 MITIGATIVE MEASURES

Mitigative measures to reduce the risk of accidents and reduce the risk of release of a toxin in the event of an accident at the proposed BL-3 laboratory were discussed in Section 2.3 on Safeguards. These mitigative safety measures include safety management programs, staff training, designated safety personnel, secured areas, SOPs for handling toxins, laboratory design including special hoods, exhaust filtration systems, and holding tanks attached to drains to contain any spills. The DA will also conduct semi-annual inspections and other periodic, random, DA-initiated inspections, reviews, staff assistance visits, etc., to insure that the safety procedures are being followed as specified in SOPs and that the equipment meets appropriate safety standards.

As discussed in the effects section, if an MCE accident occurred causing release of toxin, the total amount released before dilution in ambient air is below the level considered safe for human inhalation. Thus, no additional mitigation is necessary.

Should a MCE occur, the public would be informed of the extent and magnitude of the event. This is perhaps the best way to discourage the dissemination of incorrect information and eliminate the formation of unfounded socioeconomic concerns.

5.6 IMPACT SUMMARY MATRIX FOR ALTERNATIVES

This section and Table 5-1 summarize the environmental impacts of the proposed action (including both normal operations and the MCE scenario) and five alternative actions. No adverse impact on human health or biota is anticipated to result from either normal operations or the MCE. Impacts from normal operations include release of insignificant levels of air and water emissions (not toxins) at levels below permitted limits (see Sections 2.4.1 and 2.4.2) and the consumption of electricity and natural gas (see Section 5.5.7). Up to eight staff members could be added for the laboratory, which will have no appreciable effect on the local economy (see

TABLE 5-1. SUMMARY OF POTENTIAL IMPACTS AND REASONABLE ALTERNATIVES ASSOCIATED WITH THE PROPOSED ACTION

Potential Impact Areas[a]	Proposed Action: Build Facility at Battelle	Reasonable Alternatives to the Proposed Action				
		Use Existing DA Facility[b] (no action alternative)	Parenteral Exposure	Refined Screening Process	*In Vitro* Testing	Other Contractor[b]
Direct Impacts:						
Air Emissions	Below OEPA permitted limits (see Sect. 2.4.1)	Presumably in compliance with all permit limits	Below OEPA permitted limits	Below OEPA permitted limits	Below OEPA permitted limits	Presumably will comply with applicable regs
Water Emissions	Below OEPA permitted limits (see Sect. 2.4.2)	Presumably in compliance with all permit limits	Below OEPA permitted limits	Below OEPA permitted limits	Below OEPA permitted limits	Presumably will comply with applicable regs
Effects on Human Health	No effects; MCE below estimated MPD (see Sect. 5.3 and 5.4.1)	No new effects	No effects	No effects	No effects	Effects unknown
Effects on Biota	No effects (see Sect. 5.4.2)	No new effects	No effects	No effects	No effects	Effects unknown
Indirect Impacts:						
Socioeconomic	No effect; minimal additional staff employed (see Sect. 5.5.1)	Possible employment of minimal number of additional staff at DA facility	No effect; minimal additional staff employed	No effect; minimal additional staff employed	No effect; minimal additional staff employed	Possible employment of staff in area where lab is located
	Timely development and FDA approval of effective BW medical countermeasures needed for national defense (see Sect. 3.0)	Delays in development of BW medical countermeasures due to backlog at DA facility	Delays in development of BW medical countermeasures needed for national defense, because tests don't represent field exposure	Delays in development of BW medical countermeasures needed for national defense, because validated technology is not available	Delays in development of BW medical countermeasures needed for national defense, because tests don't correlate with field exposure	Delays in development of effective medical countermeasures needed for national defense, due to unavailability of other contractors
Cultural and Historic Resources	No effect (none present; see Sect. 5.5.2)	No new effects	No effect (none present)	No effect (none present)	No effect (none present)	Effects unknown
Land Use Conflicts	None (Sect. 5.5.3)	Presumably none	None	None	None	Unknown
Energy Requirements	Annually: 1,104,000 kWh of electricity and 5.431 mcf of natural gas (see Sect. 5.5.7)	Unknown (presumably unchanged from current operations)	Lower than proposed action because only BL-2 facility required	Same as proposed action	Lower than proposed action because only BL-2 facility required	Unknown

[a] Includes both normal operations and hypothetical MCE accident.
[b] Includes only normal operations because MCEs were not evaluated for these alternatives.

Section 5.5.1). No effects on cultural or historic resources and no land use conflicts are expected, since an existing building will be renovated (see Sections 5.5.2 and 5.5.3). A major positive effect is the expedient development and FDA approval of effective medical countermeasures for BW agents which contributes to national security.

Effects associated with the MCE accident are not expected to be significant. Only minute quantities (O.9 pg) of toxin would be released from the ventilation discharge point. Even prior to dispersion of the toxin in the atmosphere, the quantities of toxin that would be released in the MCE are much lower than the estimated dose (10 pg) that is safe for human exposure (see Section 5.4.1). Because the released quantities are so low, no effects on biota are anticipated (see Section 5.4.2).

The alternatives to using existing DA facilities will not avoid the air and water emissions and consumption of electricity and natural gas. However, a major negative impact of these alternatives is that the development and FDA approval of much needed medical countermeasures for BW agents would be slowed, having a negative effect on national security.

The alternatives to use parenteral exposure or *in vitro* testing decrease the quantities of toxin used and eliminate the use of aerosols which would lessen the MCE and would only require BL-2 biocontainment. Also, *in vitro* testing eliminates the costs associated with housing and caring for laboratory animals. The disadvantage of these alternatives is that they do not mimic the field route of exposure, and thus, would delay development and approval of medical countermeasures for BW agents, resulting in a negative impact on national defense.

The alternative to use a refined screening process (i.e., combined *in vivo* testing and computer simulation) could decrease the amount of toxin used in testing, which would reduce the MCE. However, no validated technology currently exists to evaluate the treatment efficacy parameters that would be

required in these tests. The development of such procedures *de novo* would result in delays in the development and approval of medical countermeasures needed for national defense.

5.7 REFERENCES

5.7.1 REFERENCE DOCUMENTS

Ames, Carol. 1992. Madison County Commissioner's Office, personal communication with Susan Brauning, November 6, 1992.

Bellrose, F.C., 1976. Ducks, Geese, & Swans of North America. Stackpole Books, Harrisburg, PA.

Boroff, D.A. and J.R. Reilly, 1959. Studies of the Toxin of *Clostridium botulinum*. V. Prophylactic Immunization of Pheasants and Ducks Against Avian Botulism. *J Bacteriol*, 77(2):142-146.

Gill, D.M., 1982. Bacterial Toxins: A Table of Lethal Amounts. *Microbiol Rev*, 46, 86-94.

Hastings, Judy. 1992. Madison County Zoning Office, personal communication with Susan Brauning, November 9, 1992.

Holzer, E., 1962. Botulism Caused by Inhalation. *Med Klin*, 41, 1735-1740.

Hunter, B.F., W.E. Clark, P.J. Perkins, and P.R. Coleman, 1970. Applied Botulism Research Including Management Recommendations. Calif. Dep. Fish & Game, Wildl. Manage. Prog. Rep. 87 pp.

Jensen, W.I. and C.S. Williams, 1964. Botulism and Fowl Cholera. Pages 333-341. *In:* J.P. Linduska and A.L. Nelson (Eds.), Waterfowl Tomorrow. Fish and Wildlife Service, U.S. Department of the Interior, Washington, DC.

Joklik, W.K., H.P. Willett, D.B. Amos, and C.M. Wilfert, C.M. (Eds.), 1988. Zinsser Microbiology, 19th ea., Appleton & Lange, Norwalk, CT, pp. 548-55.

Kao, I., B. Drachman, and D.L. Price, 1976. Botulinum Toxin: Mechanism of Presynaptic Blockade. *Science*, 193, 1256-1258.

Lamanna, C., 1959. The Most Poisonous Poison. *Science*, 130, 763-772.

Lamanna, C., and C.J. Carr, 1967. The Botulinal, Tetanal, and Enterostaphylococcal Toxins: A Review. *Clin Pharmac Ther*, 8, 286-332.

Moulton D.W. , W. I. Jensen, and J.B. Low, 1976. Avian Botulism Epizootiology on Sewage Oxidation Ponds in Utah. *J Wildl Manage*, 40(4):735-742.

National Institute of Health (NIH), 1990. Clinical Use of Botulinum Toxin. [Reprinted from NIH Consens Dev Conf Consens Statement 1990 Nov 12-14, 8(8)]

Riemann, H., 1973. Botulinum Food Poisoning. *Canad Inst Food Sci Tech J*, 6, 112-25.

Sakaguchi, G., 1983. *Clostridium botulinum* Toxins. *Pharmac Ther*, 19, 165-194.

Savino, P.J. and M. Maus, 1991. Botulinum Toxin Therapy. *Neurol Clinics*, 9, 205-224.

Scott, A.B., 1981. Botulinum Toxin Injection of Eye Muscles to Correct Strabismus, *Trans Am Ophth Soc*, 79, 734-770.

Sigma Chemical Company, 1991. Material Safety Data Sheet, Botulinum A. Sigma Chemical Company, Saint Louis, MO.

Sugiyama, H., 1980. *Clostridium botulinum* Neurotoxin. *Microbiol Rev*, 44, 419-448.

Truong, D.D., 1991. Botulinum Toxin Therapy. *West J Med*, 155, 69-70.

U.S. Army Medical Research and Development Command (USAMRDC), 1989. Final Programmatic Environmental Impact Statement, Biological Defense Research Program. AD-A208 851. Department of the Army, U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, MD. April.

U.S. Department of the Army, 1988. Environmental Effects of Army Actions. Army Regulation (AR) 200-2, Update, Headquarters, Department of the Army, Washington, D.C. 23 December. UNCLASSIFIED Report.

5.7.2 STATUTES AND REGULATIONS

57 FR 11368, 1992. 32 CFR Part 626, Biological Defense Safety Program, 57(64) Thursday, April 2.

6.0 LIST OF PREPARERS AND AGENCIES AND PERSONS CONSULTED

6.1 LIST OF PREPARERS

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7.0 CONCLUSIONS

This EA has examined the potential for environmental impacts of establishment and operation of a BL-3 laboratory to evaluate the efficacy of candidate medical countermeasures in preventing the effects of toxins that could be used against U.S. troops in BW by a hostile force. The proposed research sponsored by USAMRDC will be conducted at Battelle's West Jefferson research complex. The focus of the EA was to evaluate potential health and safety-related effects on the human environment. Other issues considered include effects on biota, socioeconomics, cultural and historical resources, land use conflicts, and energy consumption. Additional analyses required by NEPA that were addressed include determination of: unavoidable effects, short-term use versus long-term productivity of the environment, and irreversible and irretrievable commitment of resources. Procedural, engineering, and managerial safeguards ensure the mitigation of effects associated with normal operations. These safeguards include: safety management, safety staff, staff safety training, facility monitoring, SOPs, and protective clothing; specialized laboratories, fume hoods and air filtration equipment, and redundant power supplies; protective equipment; strict hygienic, staffing, handling, decontamination, transport, and disposal procedures; and personnel, facility, and site security.

This EA finds that no significant adverse impact on human health or the environment is anticipated from BL-3 facility establishment, normal operations, or in the unlikely event of a MCE accident. If an MCE should occur, only minute quantities (O.9 pg.) of toxin would be released from the ventilation discharge point. Even before dilution in the atmosphere, the MCE release quantity is far below the estimated MPD of 10 pg, which is the level considered to be safe for human exposure. Impacts from normal operations include release of insignificant levels of air and water emissions (not toxins) at levels below permitted limits and the consumption of electricity and natural gas. Up to eight staff members could be added for the facility, which will have no appreciable effect on the local economy. No effects on cultural or historic resources and no land use conflicts are expected, since an existing building will be renovated.

Five alternatives to the proposed action were considered: use an existing DA facility instead of Battelle (no action alternative), use parenteral exposure to avoid aerosol generation, use a refined screening procedure to reduce aerosolized toxin, use *in vitro* rather than *in vivo* tests, and use a contractor other than Battelle. From a national defense standpoint, the major advantage of the proposed action compared to all five alternatives is the expedient development and FDA approval of effective medical countermeasures to protect against toxin threats to U.S. troops.

The advantage of the alternatives to use an existing DA facility or a contractor other than Battelle would be to eliminate the remote possibility of an accident at the Battelle laboratory. The disadvantages of these two alternatives is that they would shift the accident possibility to the DA or contractor facility, lose the option of using Battelle's extensive GLP expertise and aerosol generation technology, and delay development and approval of medical countermeasures for toxins.

The advantages of the alternatives to use parenteral exposure or *in vitro* testing would be to decrease the quantities of toxin used and eliminate the use of aerosols, which would lessen the MCE and would only require BL-2 biocontainment. The disadvantages of these two alternatives is that they do not mimic the field route of exposure and they would delay development and approval of medical countermeasures for toxins.

The alternative to use a refined screening process could decrease the amount of toxin used in testing, which would reduce the MCE. The disadvantages of this alternative is that no validated technology exists to evaluate the therapeutic efficacy parameters that would be used in these tests and the *de novo* development of such procedures would, therefore, delay development and approval of medical countermeasures for toxins.

8.0 GLOSSARY

AAALAC	American Association for Accreditation of Laboratory Animal Care
ac-ft	Acre-feet
ACh	Acetylcholine
ANSI	American National Standards Institute
AR	Army regulation
biota	Various biological species of plants and animals; the flora and fauna of a region
BDRP	(DoD) Biological Defense Research Program
BL-2	Biosafety Level 2 - Practices, safety equipment, and facilities that are applicable for clinical, diagnostic, or teaching facilities in which work is done with a wide range of moderate-risk microorganisms
BL-3	Biosafety Level 3 - Practices, safety equipment, and facilities that are applicable to clinical, diagnostic, teaching, research, or production facilities for work with indigenous or exotic agents, including aerosols of toxins, where there is a potential for serious lethal consequences; the safety features of a BL-3 are not as stringent as those of BL-4
BL-4	Biosafety Level 4 - Practices, safety equipment, and facilities that are applicable to work with dangerous and exotic agents that pose a high individual risk of life-threatening disease; the highest level in a series of four increasingly stringent designs developed by CDC/NIH
Btu/ft^2	British thermal unit per square foot
BW	Biological warfare
CDC	Centers for Disease Control and Prevention
CEQ	Council on Environmental Quality
CFR	Code of federal Regulations

Class I Biological Safety Cabinet	Open-fronted, negative-pressure, ventilated cabinet exhaust air is filtered by HEPA filters
Class III Biological Safety Cabinet	Totally enclosed, ventilated cabinet of gas-tight construction; operations are conducted through attached rubber gloves. Supply air is drawn through HEPA filters and cabinet exhaust air is filtered by two HEPA filters
DA	Department of the Army
DoD	U.S. Department of Defense
DOP	di-Octyl phthalate
DOT	U.S. Department of Transportation
EA	Environmental Assessment
EIS	Environmental Impact Statement
ELISA	Enzyme-linked immunosorbent assay
epizootic	An outbreak of disease that affects many animals throughout an area at the same time
ESHD	(Battelle's) Environmental Safety and Health Department
ES&HO	(Battelle's) Environment, Safety and Health Officer
F	Fahrenheit
FDA	U.S. Food and Drug Administration
FNSI	Finding of No Significant Impact
EPA	U.S. Environmental Protection Agency
FPEIS	Final Programmatic Environmental Impact Statement
FR	Federal Register
FSSP	Facility Safety and Security Plan
ft	Foot (feet)
ft^2	Square feet

ft/min	Feet per minute
ft^3/sec	Cubic feet per second
g	gram(s)
GLP	Good Laboratory Practice
HEPA	High efficiency particulate air filter
in vitro	Procedures outside of the living organism, e.g., involving isolated organ systems, cell culture, or bench-top analytical and medicinal chemistry
in vivo	Procedures within the living organism, e.g., involving whole animals
IP	Intraperitoneal injection
IU	International unit
kg	Kilogram(s)
kWh	Kilowatt-hours
lb/hr	Pounds per hour
MBDRP	(U.S. Army) Medical Biological Defense Research Program
MBtu/hr	Million British thermal units per hour
MCE(s)	Maximum Credible Event(s)
mcf	Million cubic feet
min	Minute(s)
MLD	Median lethal dose
MPD	Maximum permissible dose
mph	Miles per hour
MSL	Mean sea level
µg	Microgram(s) (10^{-6} g)
mg	Milligram(s) (10^{-3} g)
ng	Nanogram(s) (10^{-9} g)
ng/kg	Nanograms per kilogram

NEPA	National Environmental Policy Act
NIH	National Institutes of Health
NOAA	National Oceanic and Atmospheric Administration
NPDES	National Pollutant Discharge Elimination System
NSF	National Sanitation Foundation
OAC	Ohio Administrative Code
ODNR	Ohio Department of Natural Resources
ODNAP	Ohio Division of Natural Areas and Preserves, ODNR
OEPA	Ohio Environmental Protection Agency
OJT	On-the-job training
ORC	Ohio Revised Code
pg	Picogram(s) (10^{-12} g)
pg/kg	Picograms per kilogram
PPE	Personal protective equipment
PTI	Permit to install
PTO	Permit to operate
RAC	(Battelle's) Risk Assessment Committee
RDT&E	Research, development, test, and evaluation
RCRA	Resource Conservation and Recovery Act
ROD	Record of Decision
SC	(Battelle's) Safety Committee
SCAC	(Battelle's) Security Control and Access Center
SOP	Standing operating procedure
TOP	Technical operating procedure
toxin	A substance poisonous to other organisms produced by bacteria, fungi, reptiles, arthropods, algae and many other life forms

toxoid	A toxin that is modified to have reduced toxic properties
but is still able to	induce formation of antibodies
UPS	Uninterruptible power supply
USAMRDC	U.S. Army Medical Research and Development Command
USAMRIID	U.S. Army Medical Research Institute for Infectious Diseases
USC	U.S. Code
USDA	U.S. Department of Agriculture
USGS	U.S. Geological Survey